ΕΠΙΣΗΜΗ ΕΦΗΜΕΡΙΔΑ

ΤΗΣ ΚΥΠΡΙΑΚΗΣ ΔΗΜΟΚΡΑΤΙΑΣ

ΚΥΡΙΟ ΜΕΡΟΣ

ΤΜΗΜΑ Β

Αριθμός 5418	Παρασκευή, 17 Μαρτίου 2023	1405

Αριθμός 1558

ΕΚΔΟΣΗ ΑΔΕΙΩΝ ΠΑΡΑΣΚΕΥΗΣ/ΕΙΣΑΓΩΓΗΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΠΡΟΪΟΝΤΩΝ ΑΠΟ ΤΡΙΤΕΣ ΧΩΡΕΣ

Το Συμβούλιο Φαρμάκων, σύμφωνα με τις πρόνοιες του άρθρου 39 των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμο του 2001, και σύμφωνα με τα στοιχεία που υπέβαλε ο αιτητής, έχει εκδώσει πιο κάτω Άδεια Παρασκευής/Εισαγωγής Φαρμακευτικών Προϊόντων από τρίτες χώρες με τα πιο κάτω στοιχεία:

1. Αριθμός Άδειας: 058
   Ημερομηνία Έκδοσης Άδειας: 07/02/2022
   Ισχύει μέχρι: 06/02/2027
   Κάτοχος Άδειας: New Garden Pharma Limited
   Διεύθυνση Αλληλογραφίας: Αχαρνών 25, 2305, Λακατάμια, Λευκωσία, Κύπρος

   Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Εισαγωγή φαρμακευτικών προϊόντων από τρίτες χώρες.

2. Αριθμός Άδειας: 059
   Ημερομηνία Έκδοσης Άδειας: 07/04/2022
   Ισχύει μέχρι: 06/04/2027
   Κάτοχος Άδειας: Andreas Constantinides Pharmaceuticals Ltd
   Διεύθυνση Αλληλογραφίας: Καρπασίας 61, Άγιος Αθανάσιος, 4102, Λεμεσός

   Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Εισαγωγή φαρμακευτικών προϊόντων από τρίτες χώρες.

3. Αριθμός Άδειας: 060
   Ημερομηνία Έκδοσης Άδειας: 21/11/2022
   Ισχύει μέχρι: 20/11/2027
   Κάτοχος Άδειας: Cazacor Trading Ltd
   Διεύθυνση Αλληλογραφίας: Κρόνου 30α, 1026 Λευκωσία

   Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Εισαγωγή φαρμακευτικών προϊόντων από τρίτες χώρες.

Αριθμός 1559

ΑΝΑΝΕΩΣΕΙΣ ΑΔΕΙΩΝ ΧΟΝΔΡΙΚΗΣ ΠΩΛΗΣΗΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΠΡΟΪΟΝΤΩΝ

Το Συμβούλιο Φαρμάκων, σύμφωνα με τις πρόνοιες του άρθρου 82 των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμου του 2001, και σύμφωνα με τα στοιχεία που υπέβαλαν οι αιτητές, έχει ανανεώσει την ισχύ των πιο κάτω Άδειών Χονδρικής Πώλησης Φαρμακευτικών Προϊόντων με τα πιο κάτω στοιχεία:

1. Αριθμός Άδειας: 080
   Ημερομηνία Έκδοσης Άδειας: 19/12/2011
   Προηγούμενη λήξη: 18/12/2021
   Ισχύει μέχρι: 18/12/2026
   Κάτοχος Άδειας: Figere Trading Ltd
   Διεύθυνση Αλληλογραφίας: Griva Digeni & 2 Riga Fereou Street, Limassol Centre, Block B, 6th floor, Flat 609, 3095, Limassol, Cyprus

2. Αριθμός Άδειας: 082
   Ημερομηνία Έκδοσης Άδειας: 24/02/2012
   Προηγούμενη λήξη: 23/02/2022
   Ισχύει μέχρι: 22/02/2027
   Κάτοχος Άδειας: KI.PA (Pharmacal) Ltd
   Διεύθυνση Αλληλογραφίας: P.O. Box 40608, 6306, Larnaca, Cyprus

3. Αριθμός Άδειας: 084
   Ημερομηνία Έκδοσης Άδειας: 31/08/2012
   Προηγούμενη λήξη: 30/08/2022
   Ισχύει μέχρι: 30/08/2027
   Κάτοχος Άδειας: Isangen Pharma Cyprus Ltd
   Διεύθυνση Αλληλογραφίας: Guricon House, 48 Inomenon Ethnon Street, Larnaca, 6042, Cyprus

4. Αριθμός Άδειας: 132
   Ημερομηνία Έκδοσης Άδειας: 25/07/2017
   Προηγούμενη λήξη: 24/07/2022
   Ισχύει μέχρι: 24/07/2027
   Κάτοχος Άδειας: Pharmafast Ltd
   Διεύθυνση Αλληλογραφίας: P.O.Box 21055, 1501 Nicosia, Cyprus

5. Αριθμός Άδειας: 131
   Ημερομηνία Έκδοσης Άδειας: 25/07/2017
   Προηγούμενη λήξη: 24/07/2022
   Ισχύει μέχρι: 24/07/2027
   Κάτοχος Άδειας: GN Neohealth Ltd
   Διεύθυνση Αλληλογραφίας: P.O.Box 21055, 1501 Nicosia, Cyprus

6. Αριθμός Άδειας: 003
   Ημερομηνία Έκδοσης Άδειας: 10/02/2003
   Προηγούμενη λήξη: 09/02/2023
   Ισχύει μέχρι: 09/02/2028
   Κάτοχος Άδειας: Pharmaceutical Trading CO Ltd
   Διεύθυνση Αλληλογραφίας: 33 Artemidos Street, 6025, Larnaca, Cyprus

7. Αριθμός Άδειας: 133
   Ημερομηνία Έκδοσης Άδειας: 01/12/2017
   Προηγούμενη λήξη: 30/11/2022
   Ισχύει μέχρι: 30/11/2027
   Κάτοχος Άδειας: Liamec Trading Ltd
   Διεύθυνση Αλληλογραφίας: 14 Lapithou Street, Office 005, 2410, Engomi, Nicosia, Cyprus

8. Αριθμός Άδειας: 004
   Ημερομηνία Έκδοσης Άδειας: 10/02/2003
   Προηγούμενη λήξη: 09/02/2023
   Ισχύει μέχρι: 09/02/2028
   Κάτοχος Άδειας: Marathon Distributors Ltd
   Διεύθυνση Αλληλογραφίας: P.O.Box 21464, Nicosia, 1509, Cyprus

9. Αριθμός Άδειας: 007
   Ημερομηνία Έκδοσης Άδειας: 10/02/2003
   Προηγούμενη λήξη: 09/02/2023
   Ισχύει μέχρι: 09/02/2028
   Κάτοχος Άδειας: Karpasia Health Products Ltd
   Διεύθυνση Αλληλογραφίας: 179, Yiannos Kranidiotis, Latsia, Nicosia, 2235, Cyprus

Αριθμός 1560

ΑΔΕΙΕΣ ΧΟΝΔΡΙΚΗΣ ΠΩΛΗΣΗΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΠΡΟΪΟΝΤΩΝ

Το Συμβούλιο Φαρμάκων σύμφωνα με τις πρόνοιες του άρθρου 82 των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμων του 2001, και σύμφωνα με τα στοιχεία που υπέβαλαν οι αιτητές, έχει εκδώσει Άδειες Χονδρικής Πώλησης Φαρμακευτικών Προϊόντων με τα πιο κάτω στοιχεία:

1. Αριθμός Άδειας: 155
   Ημερομηνία Έκδοσης Άδειας: 07/02/2022
   Ισχύει μέχρι: 06/02/2027
   Κάτοχος Άδειας: Filomedica Trading Limited
   Διεύθυνση Αλληλογραφίας: P.O.BOX 45091, 7110, Aradippou, Larnaca, Cyprus

2. Αριθμός Άδειας: 156
   Ημερομηνία Έκδοσης Άδειας: 07/04/2022
   Ισχύει μέχρι: 06/04/2027
   Κάτοχος Άδειας: Andreas Constantinides Pharmaceuticals Ltd
   Διεύθυνση Αλληλογραφίας: Karpasias 61, 4102, Agios Athanasios, Limassol, Cyprus

3. Αριθμός Άδειας: 157
   Ημερομηνία Έκδοσης Άδειας: 03/08/2022
   Ισχύει μέχρι: 02/08/2027
   Κάτοχος Άδειας: Medicair Bioscience Laboratories Cy Ltd
   Διεύθυνση Αλληλογραφίας: 75 Eleftherias, 3042 Limassol, Cyprus

4. Αριθμός Άδειας: 158
   Ημερομηνία Έκδοσης Άδειας: 21/11/2022
   Ισχύει μέχρι: 20/11/2027
   Κάτοχος Άδειας: Lifebank Ltd
   Διεύθυνση Αλληλογραφίας: P.O.Box 62275, 8062 Paphos, Cyprus

5. Αριθμός Άδειας: 159
   Ημερομηνία Έκδοσης Άδειας: 21/11/2022
   Ισχύει μέχρι: 20/11/2027
   Κάτοχος Άδειας: Kimgas Industrial And Medical Gases Ltd
   Διεύθυνση Αλληλογραφίας: 5e Agiasmaton, Dali, 2540, Nicosia, Cyprus

6. Αριθμός Άδειας: 160
   Ημερομηνία Έκδοσης Άδειας: 21/11/2022
   Ισχύει μέχρι: 20/11/2027
   Κάτοχος Άδειας: CPL Co-Pharma Ltd
   Διεύθυνση Αλληλογραφίας: P.O. Box 62410, 8064, Pafos, Cyprus

Αριθμός 1561

ΝΕΕΣ ΑΔΕΙΕΣ ΠΑΡΑΣΚΕΥΗΣ ΚΑΛΛΥΝΤΙΚΩΝ ΠΡΟΪΟΝΤΩΝ

Το Συμβούλιο Καλλυντικών, σύμφωνα με τις πρόνοιες του άρθρου 5 του περί Καλλυντικών Προϊόντων Νόμου του 2017, σύμφωνα με τις πρόνοιες των Κανονισμών 3 των περί Καλλυντικών Προϊόντων (Κανόνες Ορθής Βιομηχανικής Πρακτικής) Κανονισμών του 2004, και σύμφωνα με τα στοιχεία που υπέβαλαν οι αιτητές, έχει εκδώσει τις πιο κάτω Άδειες Παρασκευής Καλλυντικών Προϊόντων με τα πιο κάτω στοιχεία:

1. Αριθμός Άδειας: 037
   Ημερομηνία Έκδοσης Άδειας: 23/12/2022
   Ισχύει μέχρι: 22/12/2027
   Κάτοχος Άδειας: ΠΑΥΛΙΝΑ ΠΛΑΤΩΝΟΣ

Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Άδεια Πλήρους Παρασκευής.

2. Αριθμός Άδειας: 038
   Ημερομηνία Έκδοσης Άδειας: 23/12/2022
   Ισχύει μέχρι: 22/12/2027
   Κάτοχος Άδειας: ΝΙΚΗ ΤΟΦΑΛΛΗ

Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Άδεια Πλήρους Παρασκευής.

Αριθμός 1562

ΑΝΑΝΕΩΣΕΙΣ ΑΔΕΙΩΝ ΠΑΡΑΣΚΕΥΗΣ/ΕΙΣΑΓΩΓΗΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΠΡΟΪΟΝΤΩΝ ΑΠΟ ΤΡΙΤΕΣ ΧΩΡΕΣ

Το Συμβούλιο Φαρμάκων, σύμφωνα με τις πρόνοιες του άρθρου 39 των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμων του 2001, και σύμφωνα με τα στοιχεία που υπέβαλαν οι αιτητές, έχει ανανεώσει την ισχύ των πιο κάτω Άδειών Παρασκευής/Εισαγωγής Φαρμακευτικών Προϊόντων από τρίτες χώρες με τα πιο κάτω στοιχεία:

1. Αριθμός Άδειας: 001
   Ημερομηνία Έκδοσης Άδειας: 02/05/2002
   Προηγούμενη λήξη: 30/04/2022
   Ισχύει μέχρι: 30/04/2027
   Κάτοχος Άδειας: Mundipharma Pharmaceuticals Ltd
   Διεύθυνση Αλληλογραφίας: Τ.Θ. 23661, 1685, Λευκωσία

   Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Εργασίες Πλήρους Παρασκευής.

2. Αριθμός Άδειας: 050
   Ημερομηνία Έκδοσης Άδειας: 21/08/2017
   Προηγούμενη λήξη: 20/08/2022
   Ισχύει μέχρι: 20/08/2027
   Κάτοχος Άδειας: GN Neohealth Ltd
   Διεύθυνση Αλληλογραφίας: Τ.Θ.21055, 1501 Λευκωσία

   Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Εργασίες Μερικής Παρασκευής (Δευτερογενής Συσκευασία).

3. Αριθμός Άδειας: 007
   Ημερομηνία Έκδοσης Άδειας: 05/08/2002
   Προηγούμενη λήξη: 04/08/2022
   Ισχύει μέχρι: 04/08/2027
   Κάτοχος Άδειας: The Star Medicines Importers Co, Ltd
   Διεύθυνση Αλληλογραφίας: Τ.Θ. 50151, 3601 Λεμεσός

   Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Εισαγωγή φαρμακευτικών προϊόντων από τρίτες χώρες.

4. Αριθμός Άδειας: 015
   Ημερομηνία Έκδοσης Άδειας: 11/11/2002
   Προηγούμενη λήξη: 10/11/2022
   Ισχύει μέχρι: 10/11/2027
   Κάτοχος Άδειας: Lifepharma (ZAM) Ltd
   Διεύθυνση Αλληλογραφίας: Τ.Κ. 22679, 1523, Λευκωσία

   Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Εισαγωγή φαρμακευτικών προϊόντων από τρίτες χώρες.

5. Αριθμός Άδειας: 049
   Ημερομηνία Έκδοσης Άδειας: 21/08/2017
   Προηγούμενη λήξη: 20/08/2022
   Ισχύει μέχρι: 20/08/2027
   Κάτοχος Άδειας: A. Potamitis Medicare Ltd
   Διεύθυνση Αλληλογραφίας: Λεωφόρος Αρχ. Κυπριανού 62, 2059, Στρόβολος, Λευκωσία

   Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Εισαγωγή φαρμακευτικών προϊόντων από τρίτες χώρες.

Αριθμός 1563

ΑΝΑΝΕΩΣΕΙΣ ΑΔΕΙΩΝ ΚΥΚΛΟΦΟΡΙΑΣ ΠΟΥ ΕΧΟΥΝ ΕΓΚΡΙΘΕΙ ΑΠΟ ΤΟ ΣΥΜΒΟΥΛΙΟ ΦΑΡΜΑΚΩΝ

Το Συμβούλιο Φαρμάκων,

- σύμφωνα με τις πρόνοιες του άρθρου 34 των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμων του 2001 έως 2007,
- σύμφωνα με τα στοιχεία που υπέβαλαν οι αιτητές με τις αρχικές τους αιτήσεις, και
- σύμφωνα με τις τροποποιήσεις που υποβλήθηκαν στο μεταξύ διάστημα και έγιναν αποδεκτές,

ανανεώνει την ισχύ των Αδειών Κυκλοφορίας Φαρμακευτικών Προϊόντων με τα πιο κάτω στοιχεία:

Αρ. Άδειας Κυκλοφορίας	Όνομα Φαρμακευτικού Προϊόντος	Κάτοχος Άδειας Κυκλοφορίας	Ισχύς Άδειας
022764	AMOXAPEN TABLET, DISPERSIBLE 250MG	REMEDICA LTD	Επ' αόριστον
022611	BRADIREM TABLET, FILM COATED 5MG	REMEDICA LTD	Επ' αόριστον
022612	BRADIREM TABLET, FILM COATED 7.5MG	REMEDICA LTD	Επ' αόριστον
022483	CODALIS TABLET, FILM COATED 10MG	CODAL-SYNTO LIMITED	Επ' αόριστον
022484	CODALIS TABLET, FILM COATED 20MG	CODAL-SYNTO LIMITED	Επ' αόριστον
022482	CODALIS TABLET, FILM COATED 5MG	CODAL-SYNTO LIMITED	Επ' αόριστον
21965	EBRILON TABLET, FILM COATED 5MG	MEDOCHEMIE LTD	Επ' αόριστον
022613	ENTEVIREM TABLET, FILM COATED 0.5MG	REMEDICA LTD	Επ' αόριστον
022614	ENTEVIREM TABLET, FILM COATED 1MG	REMEDICA LTD	Επ' αόριστον
022808	EPIBAL CAPSULE, HARD 150MG	DELORBIS PHARMACEUTICALS LTD	Επ' αόριστον
022805	EPIBAL CAPSULE, HARD 25MG	DELORBIS PHARMACEUTICALS LTD	Επ' αόριστον
022806	EPIBAL CAPSULE, HARD 50MG	DELORBIS PHARMACEUTICALS LTD	Επ' αόριστον
022807	EPIBAL CAPSULE, HARD 75MG	DELORBIS PHARMACEUTICALS LTD	Επ' αόριστον
020545	FLUDARA TABLET, FILM COATED 10MG	GENZYME EUROPE B.V.	Επ' αόριστον
020695	ISOTROIN CAPSULE, SOFT 10MG	IASIS PHARMACEUTICALS HELLAS SA	Επ' αόριστον
020693	ISOTROIN CAPSULE, SOFT 20MG	IASIS PHARMACEUTICALS HELLAS SA	Επ' αόριστον
022346	KIVALA TABLET, FILM COATED	REMEDICA LTD	Επ' αόριστον
022802	LATAZ-CO EYE DROPS, SOLUTION (50MCG+5MG)/ML	RAFARM S.A.	Επ' αόριστον
022766	MEDAXONUM LIDO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1G/VIAL	MEDOCHEMIE LTD	Επ' αόριστον
022765	MEDAXONUM LIDO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500MG/VIAL	MEDOCHEMIE LTD	Επ' αόριστον
022339	MEMINI TABLET, FILM COATED 10MG	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
022340	MEMINI TABLET, FILM COATED 20MG	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
012403	NEOSTIGMIN SOLUTION FOR INJECTION 2.5MG/1ML	COOPER SA	Επ' αόριστον
020973	OXYNORM CONCENTRATE ORAL SOLUTION 10MG/ML	MUNDIPHARMA PHARMACEUTICALS LTD	Επ' αόριστον
020972	OXYNORM LIQUID ORAL SOLUTION 5MG/5ML	MUNDIPHARMA PHARMACEUTICALS LTD	Επ' αόριστον

022811	PAZOCTAM POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/ VIAL	SAPIENS PHARMACEUTICALS LTD	Επ' αόριστον
022763	PENOPEN TABLET, FILM COATED 1G	REMEDICA LTD	Επ' αόριστον
022762	PENOPEN TABLET, FILM COATED 800MG	REMEDICA LTD	Επ' αόριστον
022490	PIMAXEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	CODAL-SYNTO LIMITED	Επ' αόριστον
022491	PIMAXEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G/VIAL	CODAL-SYNTO LIMITED	Επ' αόριστον
022489	PIMAXEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	CODAL-SYNTO LIMITED	Επ' αόριστον
021942	RAZIMAX TABLET, FILM COATED 600MG	RAFARM S.A.	Επ' αόριστον
022275	REGAINE MEN'S FOAM CUTANEOUS FOAM 5% W/W	JOHNSON & JOHNSON HELLAS CONSUMER AE	Επ' αόριστον
022803	SADERON TABLET, FILM COATED 2.5MG	DELORBIS PHARMACEUTICALS LTD	Επ' αόριστον
021191	SYNTOCEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	CODAL-SYNTO LIMITED	Επ' αόριστον
022049	TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 200MG/VIAL	DEMO S.A.	Επ' αόριστον
022050	TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 400MG/VIAL	DEMO S.A.	Επ' αόριστον
022615	TREBON-N LOZENGE 600MG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
022699	TRINISTEM TABLET, FILM COATED 600MG/200MG/245MG	REMEDICA LTD	Επ' αόριστον
022213	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	SAPIENS PHARMACEUTICALS LTD	Επ' αόριστον
022729	XYLOCREAM CREAM (2.5+2.5)% W/W	VERISFIELD SINGLE MEMBER S.A.	Επ' αόριστον
021827	ZINFECT TABLET, FILM COATED 250MG	VERISFIELD SINGLE MEMBER S.A.	Επ' αόριστον
021828	ZINFECT TABLET, FILM COATED 500MG	VERISFIELD SINGLE MEMBER S.A.	Επ' αόριστον
021829	ZINFECT TABLET, FILM COATED 600MG	VERISFIELD SINGLE MEMBER S.A.	Επ' αόριστον
022693	TADALAFIL ACCORD TABLET, FILM COATED 5MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
020206	GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	GRIFOLS DEUTSCHLAND GMBH.	Επ' αόριστον
023124	GENEMENT TABLET, FILM COATED 20MG	SAPIENS PHARMACEUTICALS LTD	Επ' αόριστον
023123	GENEMENT TABLET, FILM COATED 5MG	SAPIENS PHARMACEUTICALS LTD	Επ' αόριστον
023030	SKUDEXA GRANULES FOR ORAL SOLUTION 75MG/25MG	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	Επ' αόριστον
023256	BIORPHEN SOLUTION FOR INJECTION 10MG/ML	SINTETICA GMBH	Επ' αόριστον
023255	BIORPHEN SOLUTION FOR INJECTION OR INFUSION 0.1MG/ML	SINTETICA GMBH	Επ' αόριστον
022896	LOMEXIN VAGINAL CAPSULE, SOFT 200MG	RECORDATI IRELAND LTD	Επ' αόριστον
022897	LOMEXIN VAGINAL CAPSULE, SOFT 600MG	RECORDATI IRELAND LTD	Επ' αόριστον
022730	CLARISCAN SOLUTION FOR INJECTION 0.5MMOL/ML	GE HEALTHCARE AS	Επ' αόριστον
023303	BETAHISTINE AUROBINDO TABLET 8MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον

022563	SOLPADEINE HEADACHE EFFERVESCENT TABLET 500MG/65MG	OMEGA PHARMA HELLAS S.A	Επ' αόριστον
022400	BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	ABBVIE PHARMACEUTICALS S.A.	Επ' αόριστον
022401	BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	ABBVIE PHARMACEUTICALS S.A.	Επ' αόριστον
022399	BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	ABBVIE PHARMACEUTICALS S.A.	Επ' αόριστον
022904	ROZOR TABLET, FILM COATED 10MG/10MG	VIATRIS HEALTHCARE LIMITED.	Επ' αόριστον
022905	ROZOR TABLET, FILM COATED 20MG/10MG	VIATRIS HEALTHCARE LIMITED.	Επ' αόριστον
022309	PHYSIONEAL 35 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	BAXTER (HELLAS) EPE	Επ' αόριστον
022310	PHYSIONEAL 35 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	BAXTER (HELLAS) EPE	Επ' αόριστον
022311	PHYSIONEAL 35 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86% W/V	BAXTER (HELLAS) EPE	Επ' αόριστον
022312	PHYSIONEAL 40 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	BAXTER (HELLAS) EPE	Επ' αόριστον
022313	PHYSIONEAL 40 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	BAXTER (HELLAS) EPE	Επ' αόριστον
022314	PHYSIONEAL 40 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86%	BAXTER (HELLAS) EPE	Επ' αόριστον
022601	METRONIDAZOLE VIOSER SOLUTION FOR INFUSION 500MG/100ML	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	Επ' αόριστον
023221	VIZITRAV EYE DROPS, SOLUTION 40MCG/ML	BAUSCH + LOMB IRELAND LIMITED	Επ' αόριστον
023376	HEXARHINAL PLUS NASAL SPRAY, SOLUTION (1MG/50MG)/ML	JOHNSON & JOHNSON HELLAS CONSUMER AE	Επ' αόριστον
023309	LAMIVUDINE/ZIDOVUDINE ACCORD TABLET, FILM COATED 150MG/300MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
021396	FLUTIFORM PRESSURISED INHALATION, SUSPENSION 125MCG/5MCG	MUNDIPHARMA PHARMACEUTICALS LTD	Επ' αόριστον
021397	FLUTIFORM PRESSURISED INHALATION, SUSPENSION 250MCG/10MCG	MUNDIPHARMA PHARMACEUTICALS LTD	Επ' αόριστον
021395	FLUTIFORM PRESSURISED INHALATION, SUSPENSION 50MCG/5MCG	MUNDIPHARMA PHARMACEUTICALS LTD	Επ' αόριστον
022853	BILAZ ORAL SOLUTION 2.5MG/ML	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	Επ' αόριστον
022371	SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022372	SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023571	ERTAPENEM APTAPHARMA POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 1G	APTA MEDICA INTERNACIONAL D.O.O.	Επ' αόριστον
022711	DALTEX TABLET, FILM COATED 50MG/1000MG	MEDOCHEMIE LTD	Επ' αόριστον
022710	DALTEX TABLET, FILM COATED 50MG/850MG	MEDOCHEMIE LTD	Επ' αόριστον
023377	IMIPENEM/CILASTATIN APTAPHARMA POWDER FOR SOLUTION FOR INFUSION 500MG/500MG	APTA MEDICA INTERNACIONAL D.O.O.	Επ' αόριστον
023537	SCABALL TABLET 3MG	EPSILON HEALTH (NESTORAS VLACHOS P.C.)	Επ' αόριστον

022511	TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	SANOFI PASTEUR.	Επ' αόριστον
022831	JIMANDIN TABLET, FILM COATED 100MG	MEDOCHEMIE LTD	Επ' αόριστον
022829	JIMANDIN TABLET, FILM COATED 25MG	MEDOCHEMIE LTD	Επ' αόριστον
022830	JIMANDIN TABLET, FILM COATED 50MG	MEDOCHEMIE LTD	Επ' αόριστον
023442	AFEKSIN SOLUBLE TABLET 20MG	TEVA BV	Επ' αόριστον
023283	SMOFKABIVEN EXTRA NITROGEN ELECTROLYTE FREE EMULSION FOR INFUSION	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	Επ' αόριστον
023282	SMOFKABIVEN EXTRA NITROGEN EMULSION FOR INFUSION	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	Επ' αόριστον
023443	HYDROCORTISONE RENATA TABLET 10MG	RENATA PHARMACEUTICALS (IRELAND) LIMITED	Επ' αόριστον
023444	HYDROCORTISONE RENATA TABLET 20MG	RENATA PHARMACEUTICALS (IRELAND) LIMITED	Επ' αόριστον
023227	NANOGAM SOLUTION FOR INFUSION 100MG/ML	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	Επ' αόριστον
022441	VALSIMIA TABLET, FILM COATED 10MG/160MG	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
022440	VALSIMIA TABLET, FILM COATED 5MG/160MG	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
022439	VALSIMIA TABLET, FILM COATED 5MG/80MG	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
022714	KANILAD TABLET, FILM COATED 100MG	MEDOCHEMIE LTD	Επ' αόριστον
022715	KANILAD TABLET, FILM COATED 150MG	MEDOCHEMIE LTD	Επ' αόριστον
022716	KANILAD TABLET, FILM COATED 200MG	MEDOCHEMIE LTD	Επ' αόριστον
022713	KANILAD TABLET, FILM COATED 50MG	MEDOCHEMIE LTD	Επ' αόριστον
021717	YODAFAR TABLET 200MCG	BIAL-PORTELA & CA, SA	Επ' αόριστον
023129	NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	JOHNSON & JOHNSON HELLAS CONSUMER AE	Επ' αόριστον
022395	GAVISCON STRAWBERRY FLAVOUR TABLET, CHEWABLE	RECKITT BENCKISER HELLAS HEALTHCARE SA	Επ' αόριστον
023260	IDARUBICIN ACCORD SOLUTION FOR INJECTION 10MG/10ML	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023261	IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023259	IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022915	SOFTACORT EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 3.35MG/ML	LABORATOIRES THEA	Επ' αόριστον
021718	YODAFAR TABLET 300MCG	BIAL-PORTELA & CA, SA	Επ' αόριστον
021972	NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	RAFARM S.A.	Επ' αόριστον
023037	GLATIRAMER/MYLAN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	MYLAN IRELAND LIMITED	Επ' αόριστον
023284	VERTIGO-N TABLET 20MG/40MG	GALENICA SA	Επ' αόριστον
023333	FLUOXETINE AUROBINDO CAPSULE, HARD 20MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022828	MONOPROST EYE DROPS, SOLUTION 50MCG/ML	LABORATOIRES THEA	Επ' αόριστον
022382	VENLAFAXINE/UPJOHN CAPSULE, HARD, PROLONGED-RELEASE 150MG	UPJOHN HELLAS LTD	Επ' αόριστον
022380	VENLAFAXINE/UPJOHN CAPSULE, HARD, PROLONGED-RELEASE 37.5MG	UPJOHN HELLAS LTD	Επ' αόριστον

022381	VENLAFAXINE/UPJOHN CAPSULE, HARD, PROLONGED-RELEASE 75MG	UPJOHN HELLAS LTD	Επ' αόριστον
022623	NEVIRAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022625	ROSUVADOR TABLET, FILM COATED 10MG	TAD PHARMA GMBH	Επ' αόριστον
022626	ROSUVADOR TABLET, FILM COATED 20MG	TAD PHARMA GMBH	Επ' αόριστον
022627	ROSUVADOR TABLET, FILM COATED 40MG	TAD PHARMA GMBH	Επ' αόριστον
022624	ROSUVADOR TABLET, FILM COATED 5MG	TAD PHARMA GMBH	Επ' αόριστον
022779	BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.1MG/ML	PHARMATHEN S.A.	Επ' αόριστον
022780	BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.3MG/ML	PHARMATHEN S.A.	Επ' αόριστον
022781	PARACETAMOL/KABI SOLUTION FOR INFUSION 10MG/ML	FRESENIUS KABI HELLAS A.E.	Επ' αόριστον
022810	AMLODIPIN ACCORD TABLET 10MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022809	AMLODIPIN ACCORD TABLET 5MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022951	MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/VIAL	APTA MEDICA INTERNACIONAL D.O.O.	Επ' αόριστον
022950	MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	APTA MEDICA INTERNACIONAL D.O.O.	Επ' αόριστον
021393	MEDOTIS TABLET, GASTRO-RESISTANT 10MG	ZENTIVA K.S.	Επ' αόριστον
021394	MEDOTIS TABLET, GASTRO-RESISTANT 20MG	ZENTIVA K.S.	Επ' αόριστον
022596	EPIDUO GEL (0.001G/0.025G)G	GALDERMA INTERNATIONAL,FRANCE	Επ' αόριστον
022772	TRIVERAM TABLET, FILM COATED 10MG/5MG/5MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022775	TRIVERAM TABLET, FILM COATED 20MG/10MG/10MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022774	TRIVERAM TABLET, FILM COATED 20MG/10MG/5MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022773	TRIVERAM TABLET, FILM COATED 20MG/5MG/5MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022776	TRIVERAM TABLET, FILM COATED 40MG/10MG/10MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022576	INJOSETRON SOLUTION FOR INJECTION 250MCG/5ML	RAFARM S.A.	Επ' αόριστον
022571	TADALAFIL ACCORD TABLET, FILM COATED 20MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022636	COSYREL TABLET, FILM COATED 10MG/10MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022635	COSYREL TABLET, FILM COATED 10MG/5MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022634	COSYREL TABLET, FILM COATED 5MG/10MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022633	COSYREL TABLET, FILM COATED 5MG/5MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022724	ELMIGRAIN TABLET, FILM COATED 20MG	RAFARM S.A.	Επ' αόριστον
022725	ELMIGRAIN TABLET, FILM COATED 40MG	RAFARM S.A.	Επ' αόριστον
023130	FULVESTRANT ACCORD SOLUTION FOR INJECTION IN PREFILLED SYRINGES 250MG/5ML	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
20668	ADAGREL TABLET, FILM COATED 75MG	SAPIENS PHARMACEUTICALS LTD	Επ' αόριστον
022554	PLATOREL TABLET, FILM COATED 10MG	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
022555	PLATOREL TABLET, FILM COATED 20MG	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον

022556	PLATOREL TABLET, FILM COATED 40MG	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
022553	PLATOREL TABLET, FILM COATED 5MG	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
022833	BILAZ TABLET, ORODISPERSIBLE 10MG	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	Επ' αόριστον
022204	MENTIFAR TABLET, FILM COATED 10MG	RAFARM S.A.	Επ' αόριστον
022205	MENTIFAR TABLET, FILM COATED 20MG	RAFARM S.A.	Επ' αόριστον
023180	DELAZO EYE DROPS, SOLUTION 20MG/ML	PHARMATHEN S.A.	Επ' αόριστον
023179	ORATORIA EYE DROPS, SOLUTION 1MG/ML	PHARMATHEN S.A.	Επ' αόριστον
023243	ALPRAZOLAM TAD TABLET 0.25MG	TAD PHARMA GMBH	Επ' αόριστον
023244	ALPRAZOLAM TAD TABLET 0.5MG	TAD PHARMA GMBH	Επ' αόριστον
023245	ALPRAZOLAM TAD TABLET 1MG	TAD PHARMA GMBH	Επ' αόριστον
022726	FUSIDIC ACID/BETAMETHASONE VALERATE PHARMASCIENCE INTERNATIONAL CREAM (20MG/1MG)/G	PHARMASCIENCE INTERNATIONAL LTD	Επ' αόριστον
023408	QUELORAN TABLET, PROLONGED-RELEASE 150MG	PHARMATHEN S.A.	Επ' αόριστον
023409	QUELORAN TABLET, PROLONGED-RELEASE 200MG	PHARMATHEN S.A.	Επ' αόριστον
023410	QUELORAN TABLET, PROLONGED-RELEASE 300MG	PHARMATHEN S.A.	Επ' αόριστον
023411	QUELORAN TABLET, PROLONGED-RELEASE 400MG	PHARMATHEN S.A.	Επ' αόριστον
023407	QUELORAN TABLET, PROLONGED-RELEASE 50MG	PHARMATHEN S.A.	Επ' αόριστον
023177	SALOFALK TABLET, GASTRO-RESISTANT 1G	DR. FALK PHARMA GMBH	Επ' αόριστον
022517	FUROSEMIDE ACCORD SOLUTION FOR INJECTION OR INFUSION 10MG/ML	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022522	INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022523	MYDRANE SOLUTION FOR INJECTION 0.2MG/ML+3.1MG/ML+10MG/ML	LABORATOIRES THEA	Επ' αόριστον
021507	METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 54MG	SANDOZ GMBH	Επ' αόριστον
022687	ARESTON TABLET, FILM COATED 12.5MG	MEDOCHEMIE LTD	Επ' αόριστον
022692	INFLUVAC SUB-UNIT TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	MYLAN IRE HEALTHCARE LIMITED	Επ' αόριστον
022319	PENEMNIA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	PHARMATHEN S.A.	Επ' αόριστον
022318	PENEMNIA POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	PHARMATHEN S.A.	Επ' αόριστον
023467	DIAZEPAM ACCORD TABLET 10MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023466	DIAZEPAM ACCORD TABLET 5MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023433	COLCHICINE RENATA TABLET 500MCG	RENATA PHARMACEUTICALS (IRELAND) LIMITED	Επ' αόριστον
022903	NUROFEN DURANCE MEDICATED PLASTER 200MG	RECKITT BENCKISER HELLAS HEALTHCARE SA	Επ' αόριστον
022674	ACLONIA TABLET 70MG/2800IU	PHARMATHEN S.A.	Επ' αόριστον
022675	ACLONIA TABLET 70MG/5600IU	PHARMATHEN S.A.	

Αριθμός 1564

ΑΔΕΙΕΣ ΚΥΚΛΟΦΟΡΙΑΣ ΠΟΥ ΕΧΟΥΝ ΕΚΔΟΘΕΙ ΑΠΟ ΤΟ ΣΥΜΒΟΥΛΙΟ ΦΑΡΜΑΚΩΝ

Το Συμβούλιο Φαρμάκων, σύμφωνα με τις πρόνοιες του άρθρου 9 των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμων του 2001 (70(Ι)/2001) όπως εκάστοτε τροποποιείται, και σύμφωνα με τα στοιχεία που υπέβαλαν οι αιτητές, εκδίδει Άδειες Κυκλοφορίας Φαρμακευτικών Προϊόντων με τα πιο κάτω στοιχεία:

Άρ. Άδειας Κυκλοφορίας	Όνομα Φαρμακευτικού Προϊόντος	Δραστικά Συστατικά	Κάτοχος Άδειας Κυκλοφορίας	Ημερομηνία Έκδοσης Άδειας
023665	ARTEPRO TABLET, FILM COATED 10MG	ROSUVASTATIN CALCIUM 10.4 mg	SAPIENS PHARMACEUTICALS LTD	04/07/2022
023666	ARTEPRO TABLET, FILM COATED 20MG	ROSUVASTATIN CALCIUM 20.8 mg	SAPIENS PHARMACEUTICALS LTD	04/07/2022
023667	ARTEPRO TABLET, FILM COATED 40MG	ROSUVASTATIN CALCIUM 41.6 mg	SAPIENS PHARMACEUTICALS LTD	04/07/2022
023664	ARTEPRO TABLET, FILM COATED 5MG	ROSUVASTATIN CALCIUM 5.2 mg	SAPIENS PHARMACEUTICALS LTD	04/07/2022
023710	ADVANTAN CREAM 0.1% (W/W)	METHYLPREDNISOLONE ACEPONATE 1. mg	LEO PHARMA A/S	05/09/2022
023711	ADVANTAN EMULSION, CUTANEOUS 0.1% (W/W)	METHYLPREDNISOLONE ACEPONATE 1. mg	LEO PHARMA A/S	05/09/2022
023630	WATER FOR INJECTION/MEDOCHEMIE SOLVENT FOR PARENTERAL USE 10ML	null	MEDOCHEMIE LTD	07/04/2022
023712	AZITHRAN INJECTABLE POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	AZITHROMYCIN DIHYDRATE 524.1 mg	SAPIENS PHARMACEUTICALS LTD	09/09/2022
023653	FINGOLIMOD SAPIENS CAPSULE, HARD 0.5MG	FINGOLIMOD HYDROCHLORIDE 0.56 mg	SAPIENS PHARMACEUTICALS LTD	10/06/2022
023738	ABATOR TABLET, FILM COATED 10MG	ATORVASTATIN CALCIUM TRIHYDRATE 10.85 mg	SAPIENS PHARMACEUTICALS LTD	10/11/2022
023739	ABATOR TABLET, FILM COATED 20MG	ATORVASTATIN CALCIUM TRIHYDRATE 21.7 mg	SAPIENS PHARMACEUTICALS LTD	10/11/2022
023740	ABATOR TABLET, FILM COATED 40MG	ATORVASTATIN CALCIUM TRIHYDRATE 43.4 mg	SAPIENS PHARMACEUTICALS LTD	10/11/2022

023741	ABATOR TABLET, FILM COATED 80MG	ATORVASTATIN CALCIUM TRIHYDRATE 86.8 mg	SAPIENS PHARMACEUTICALS LTD	10/11/2022
023735	PANTOPRAZOLE DELORBIS TABLET, GASTRO-RESISTANT 40MG	PANTOPRAZOLE SODIUM SESQUIHYDRATE 45.15 mg	DELORBIS PHARMACEUTICALS LTD	10/11/2022
023631	BOTAFEX CUTANEOUS SOLUTION 5% (W/V)	MINOXIDIL 50. mg	PHARMEX S.A.	11/04/2022
023632	PAZOREM TABLET, FILM COATED 200MG	PAZOPANIB HYDROCHLORIDE 216.7 mg	REMEDICA LTD	11/04/2022
023633	PAZOREM TABLET, FILM COATED 400MG	PAZOPANIB HYDROCHLORIDE 433.4 mg	REMEDICA LTD	11/04/2022
023589	NIMETAB TABLET, FILM COATED 120MG	FEBUXOSTAT 120. mg	DELORBIS PHARMACEUTICALS LTD	18/01/2022
023588	NIMETAB TABLET, FILM COATED 80MG	FEBUXOSTAT 80. mg	DELORBIS PHARMACEUTICALS LTD	18/01/2022
023636	ABIRATERONE SAPIENS TABLET, FILM COATED 500MG	ABIRATERONE ACETATE 500. mg	SAPIENS PHARMACEUTICALS LTD	18/04/2022
023639	VIDELMET TABLET, FILM COATED 50MG/1000MG	VILDAGLIPTIN 50. mg | METFORMIN HYDROCHLORIDE 1000. mg	DELORBIS PHARMACEUTICALS LTD	18/04/2022
023638	VIDELMET TABLET, FILM COATED 50MG/850MG	VILDAGLIPTIN 50. mg | METFORMIN HYDROCHLORIDE 850. mg	DELORBIS PHARMACEUTICALS LTD	18/04/2022
023757	OLOPATADINE/RAFARM EYE DROPS, SOLUTION 1MG/ML	OLOPATADINE HYDROCHLORIDE 1.11 mg	RAFARM S.A.	20/12/2022
023659	ADVANTAN CUTANEOUS SOLUTION 0.1% (W/V)	METHYLPREDNISOLONE ACEPONATE 1. mg	LEO PHARMA A/S	24/06/2022
023748	CANESTEN VAGINAL CREAM 2%	CLOTRIMAZOLE 2. g	BAYER HELLAS ABEE	25/11/2022
023724	BIRMOST-CO EYE DROPS, SOLUTION (0.3MG+5MG)/ML	BIMATOPROST 0.3 mg | TIMOLOL MALEATE 6.83 mg	RAFARM S.A.	27/09/2022
023608	LIPOCOMB CAPSULE, HARD 10MG/10MG	ROSUVASTATIN ZINC 10.68 mg | EZETIMIBE 10. mg	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	01/03/2022

023609	LIPOCOMB CAPSULE, HARD 20MG/10MG	ROSUVASTATIN ZINC 21.36 mg | EZETIMIBE 10. mg	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	01/03/2022
023646	SELGAMIS CREAM 50MCG/G	TRIFAROTENE 0.05 mg	GALDERMA INTERNATIONAL,FRANCE	01/06/2022
023702	AXIUM-OPTO EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 1MG/ML	DEXAMETHASONE SODIUM PHOSPHATE 1.093 mg	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	01/09/2022
023734	LETYBO POWDER FOR SOLUTION FOR INJECTION 50U	CLOSTRIDIUM BOTULINUM NEUROTOXIN TYPE A 50. U	CROMA-PHARMA GMBH	01/11/2022
023637	SIMDAX CONCENTRATE FOR SOLUTION FOR INFUSION 2.5 MG/ML	LEVOSIMENDAN 2.5 mg	ORION CORPORATION (ORION PHARMA)	02/05/2022
023685	IMATINIB TAD TABLET, FILM COATED 100MG	IMATINIB MESYLATE 119.5 mg	TAD PHARMA GMBH	02/08/2022
023684	IMATINIB TAD TABLET, FILM COATED 400MG	IMATINIB MESYLATE 478. mg	TAD PHARMA GMBH	02/08/2022
023705	SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 100MG/1000MG	METFORMIN HYDROCHLORIDE 1000. mg | SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE 113.38 mg	APC INSTYTUT SP. Z.O.O.	02/09/2022
023704	SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/1000MG	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE 56.69 mg | METFORMIN HYDROCHLORIDE 1000. mg	APC INSTYTUT SP. Z.O.O.	02/09/2022
023703	SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/500MG	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE 56.69 mg | METFORMIN HYDROCHLORIDE 500. mg	APC INSTYTUT SP. Z.O.O.	02/09/2022
023732	MEPIDENTAL SOLUTION FOR INJECTION IN A CARTRIDGE 30MG/ML	MEPIVACAINE HYDROCHLORIDE 30. mg	INIBSA DENTAL S.L.U.	02/11/2022

023723	PRODUODOPA SOLUTION FOR INFUSION (240MG+12MG)/ML	FOSLEVODOPA 240. mg | FOSCARBIDOPA 12. mg	ABBVIE PHARMACEUTICALS S.A.	03/10/2022
023733	PARMENOL ORAL SOLUTION 1.5MG/ML	BUTAMIRATE CITRATE 1.5 mg	MEDOCHEMIE LTD	03/11/2022
023625	FENODEX TABLET, FILM COATED 12.5MG	DEXKETOPROFEN TROMETAMOL 18.45 mg	MEDOCHEMIE LTD	04/04/2022
023626	FENODEX TABLET, FILM COATED 25MG	DEXKETOPROFEN TROMETAMOL 36.9 mg	MEDOCHEMIE LTD	04/04/2022
023687	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	PALIPERIDONE PALMITATE 156. mg	TEVA PHARMA BV	04/08/2022
023688	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	PALIPERIDONE PALMITATE 234. mg	TEVA PHARMA BV	04/08/2022
023686	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	PALIPERIDONE PALMITATE 117. mg	TEVA PHARMA BV	04/08/2022
023721	RADICUT TABLET, FILM COATED 50MG/1000MG	METFORMIN HYDROCHLORIDE 1000. mg | VILDAGLIPTIN 50. mg	GENEPHARM SA	04/10/2022
023720	RADICUT TABLET, FILM COATED 50MG/850MG	METFORMIN HYDROCHLORIDE 850. mg | VILDAGLIPTIN 50. mg	GENEPHARM SA	04/10/2022
023640	CARMUSTINE ACCORD POWDER & SOLVENT FOR CONCENTRATE FOR SOL.FOR INF. 100MG	CARMUSTINE 100. mg	ACCORD HEALTHCARE S.L.U	05/05/2022
023695	DIENOGEST BESINS TABLET 2MG	DIENOGEST 2. mg	LABORATOIRES BESINS INTERNATIONAL	05/08/2022
023693	FYLEPSIA TABLET, FILM COATED 10MG	PERAMPANEL 10. mg	ELPEN PHARMACEUTICAL CO INC	05/08/2022
023694	FYLEPSIA TABLET, FILM COATED 12MG	PERAMPANEL 12. mg	ELPEN PHARMACEUTICAL CO INC	05/08/2022
023689	FYLEPSIA TABLET, FILM COATED 2MG	PERAMPANEL 2. mg	ELPEN PHARMACEUTICAL CO INC	05/08/2022
023690	FYLEPSIA TABLET, FILM COATED 4MG	PERAMPANEL 4. mg	ELPEN PHARMACEUTICAL CO INC	05/08/2022
023691	FYLEPSIA TABLET, FILM COATED 6MG	PERAMPANEL 6. mg	ELPEN PHARMACEUTICAL CO INC	05/08/2022
023692	FYLEPSIA TABLET, FILM COATED 8MG	PERAMPANEL 8. mg	ELPEN PHARMACEUTICAL CO INC	05/08/2022
023706	LIDOCAINE HYDROCHLORIDE NORIDEM SOLUTION FOR INJECTION 10 MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE 10.66 mg	NORIDEM ENTERPRISES LTD	05/09/2022

023707	LIDOCAINE HYDROCHLORIDE NORIDEM SOLUTION FOR INJECTION 20 MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE 21.32 mg	NORIDEM ENTERPRISES LTD	05/09/2022
023652	PRORAMACE CAPSULE, HARD 10MG/10MG	BISOPROLOL FUMARATE 10. mg | RAMIPRIL 10. mg	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	06/06/2022
023651	PRORAMACE CAPSULE, HARD 10MG/5MG	BISOPROLOL FUMARATE 5. mg | RAMIPRIL 10. mg	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	06/06/2022
023647	PRORAMACE CAPSULE, HARD 2.5MG/1.25MG	BISOPROLOL FUMARATE 1.25 mg | RAMIPRIL 2.5 mg	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	06/06/2022
023648	PRORAMACE CAPSULE, HARD 2.5MG/2.5MG	RAMIPRIL 2.5 mg | BISOPROLOL FUMARATE 2.5 mg	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	06/06/2022
023649	PRORAMACE CAPSULE, HARD 5MG/2.5MG	RAMIPRIL 5. mg | BISOPROLOL FUMARATE 2.5 mg	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	06/06/2022
023650	PRORAMACE CAPSULE, HARD 5MG/5MG	BISOPROLOL FUMARATE 5. mg | RAMIPRIL 5. mg	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	06/06/2022
023582	FINRINA CAPSULE, HARD 0.5MG	FINGOLIMOD HYDROCHLORIDE 0.56 mg	GENEPHARM SA	07/01/2022
023581	REVAMOX TABLET, FILM COATED 200MG	SORAFENIB TOSILATE 274. mg	SAPIENS PHARMACEUTICALS LTD	07/01/2022
023627	TEMELOR TABLET 0.5MG	LORAZEPAM 0.5 mg	MEDOCHEMIE LTD	07/04/2022
023628	TEMELOR TABLET 1MG	LORAZEPAM 1. mg	MEDOCHEMIE LTD	07/04/2022
023629	TEMELOR TABLET 2.5MG	LORAZEPAM 2.5 mg	MEDOCHEMIE LTD	07/04/2022
023708	PIRFENIDONE MSN TABLET, FILM COATED 267MG	PIRFENIDONE 267. mg	MSN LABS EUROPE LIMITED	07/09/2022
023709	PIRFENIDONE MSN TABLET, FILM COATED 801MG	PIRFENIDONE 801. mg	MSN LABS EUROPE LIMITED	07/09/2022
023749	CHOLZET CAPSULE, HARD 10MG/10MG	ATORVASTATIN CALCIUM TRIHYDRATE 10.82 mg | EZETIMIBE 10. mg	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	07/12/2022
023750	CHOLZET CAPSULE, HARD 20MG/10MG	ATORVASTATIN CALCIUM TRIHYDRATE 21.64 mg | EZETIMIBE 10. mg	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	07/12/2022

023751	CHOLZET CAPSULE, HARD 40MG/10MG	ATORVASTATIN CALCIUM TRIHYDRATE 43.28 mg | EZETIMIBE 10. mg	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	07/12/2022
023607	ESMOBETA SOLUTION FOR INFUSION 10MG/ML	ESMOLOL HYDROCHLORIDE 10. mg	NORIDEM ENTERPRISES LTD	08/03/2022
023599	TACROLIMUS ACCORD OINTMENT 0.1%	TACROLIMUS MONOHYDRATE 1.022 mg	ACCORD HEALTHCARE S.L.U	09/02/2022
023611	DEFERASIROX PHARMATHEN TABLET, FILM COATED 180MG	DEFERASIROX 180. mg	PHARMATHEN S.A.	09/03/2022
023612	DEFERASIROX PHARMATHEN TABLET, FILM COATED 360MG	DEFERASIROX 360. mg	PHARMATHEN S.A.	09/03/2022
023610	DEFERASIROX PHARMATHEN TABLET, FILM COATED 90MG	DEFERASIROX 90. mg	PHARMATHEN S.A.	09/03/2022
023641	AZACITIDINE PHARMASCIENCE POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	AZACITIDINE 100. mg	PHARMASCIENCE INTERNATIONAL LTD	09/05/2022
023713	SUGAMMADEX ANABIOSIS SOLUTION FOR INJECTION 100MG/ML	SUGAMMADEX SODIUM 108.8 mg	ANABIOSIS PC.	09/09/2022
023586	TIORESP INHALATION POWDER, PRE-DISPENSED 10MCG/DOSE	TIOTROPIUM BROMIDE MONOHYDRATE 0.016 mg	ELPEN PHARMACEUTICAL CO INC	11/01/2022
023613	AMPICILLIN/SULBACTAM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/0.5G	AMPICILLIN SODIUM 1.063 g | SULBACTAM SODIUM 0.547 g	APTA MEDICA INTERNACIONAL D.O.O.	11/03/2022
023614	AMPICILLIN/SULBACTAM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G/1G	AMPICILLIN SODIUM 2.126 g | SULBACTAM SODIUM 1.094 g	APTA MEDICA INTERNACIONAL D.O.O.	11/03/2022
023725	NEOBRUFEN TABLET, FILM COATED 200MG	IBUPROFEN 200. mg	VIATRIS HEALTHCARE LIMITED.	11/10/2022
023726	NEOBRUFEN TABLET, FILM COATED 400MG	IBUPROFEN 400. mg	VIATRIS HEALTHCARE LIMITED.	11/10/2022
023727	NEOBRUFEN TABLET, FILM COATED 600MG	IBUPROFEN 600. mg	VIATRIS HEALTHCARE LIMITED.	11/10/2022
023728	NEOBRUFEN TABLET, PROLONGED-RELEASE 800MG	IBUPROFEN 800. mg	VIATRIS HEALTHCARE LIMITED.	11/10/2022
023642	ZETIVASIM TABLET 10MG/10MG	EZETIMIBE 10. mg | SIMVASTATIN 10. mg	ANFARM HELLAS S.A.	12/05/2022
023643	ZETIVASIM TABLET 10MG/20MG	EZETIMIBE 10. mg | SIMVASTATIN 20. mg	ANFARM HELLAS S.A.	12/05/2022

023644	ZETIVASIM TABLET 10MG/40MG	EZETIMIBE 10. mg | SIMVASTATIN 40. mg	ANFARM HELLAS S.A.	12/05/2022
023645	ZETIVASIM TABLET 10MG/80MG	EZETIMIBE 10. mg | SIMVASTATIN 80. mg	ANFARM HELLAS S.A.	12/05/2022
023670	AMIBUSIN SOLUTION FOR INJECTION 2.5 MG/ML	BUPIVACAINE HYDROCHLORIDE, MONOHYDRATE 2.64 mg	NORIDEM ENTERPRISES LTD	12/07/2022
023671	AMIBUSIN SOLUTION FOR INJECTION 5MG/ML	BUPIVACAINE HYDROCHLORIDE, MONOHYDRATE 5.28 mg	NORIDEM ENTERPRISES LTD	12/07/2022
023668	UNIGESIC TABLET 35MG/450MG	PARACETAMOL 450. mg | ORPHENADRINE CITRATE 35. mg	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	12/07/2022
023716	REMEVIA TABLET, FILM COATED 100MG	SITAGLIPTIN HYDROCHLORIDE 108.95 mg	REMEDICA LTD	12/09/2022
023714	REMEVIA TABLET, FILM COATED 25MG	SITAGLIPTIN HYDROCHLORIDE 27.2375 mg	REMEDICA LTD	12/09/2022
023715	REMEVIA TABLET, FILM COATED 50MG	SITAGLIPTIN HYDROCHLORIDE 54.475 mg	REMEDICA LTD	12/09/2022
023634	BENDAMUSTINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	BENDAMUSTIN HYDROCHLORIDE MONOHYDRATE 26.14 mg	ACCORD HEALTHCARE S.L.U	13/04/2022
023669	LOCERYL MEDICATED NAIL LACQUER 5% (W/V)	AMOROLFINE HYDROCHLORIDE 5.574 % (W/V)	GALDERMA INTERNATIONAL,FRANCE	13/07/2022
023672	STERCORE TABLET, FILM COATED 1MG	PRUCALOPRIDE SUCCINATE 1.32 mg	MEDOCHEMIE LTD	13/07/2022
023673	STERCORE TABLET, FILM COATED 2MG	PRUCALOPRIDE SUCCINATE 2.64 mg	MEDOCHEMIE LTD	13/07/2022
023600	PADLAS TABLET 50MG	VILDAGLIPTIN 50. mg	ELPEN PHARMACEUTICAL CO INC	14/02/2022
023674	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 375MG	RANOLAZINE 375. mg	ELC GROUP S.R.O.	14/07/2022
023675	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 500MG	RANOLAZINE 500. mg	ELC GROUP S.R.O.	14/07/2022

023676	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 750MG	RANOLAZINE 750. mg	ELC GROUP S.R.O.	14/07/2022
023729	ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	ZOLEDRONIC ACID MONOHYDRATE 42.64 mg	ALTAN PHARMACEUTICALS S.A.	14/10/2022
023730	ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 5MG/100ML	ZOLEDRONIC ACID MONOHYDRATE 53.3 mg	ALTAN PHARMACEUTICALS S.A.	14/10/2022
023605	JIDINUM TABLET, FILM COATED 100MG	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE 113.4 mg	MEDOCHEMIE LTD	15/02/2022
023603	JIDINUM TABLET, FILM COATED 25MG	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE 28.35 mg	MEDOCHEMIE LTD	15/02/2022
023604	JIDINUM TABLET, FILM COATED 50MG	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE 56.7 mg	MEDOCHEMIE LTD	15/02/2022
023602	PARACETAMOL/BAXTER VIAFLO SOLUTION FOR INFUSION 10 MG/ML	PARACETAMOL 10. mg	BAXTER HOLDING B.V.	15/02/2022
023677	TRAMADOL/PARACETAMOL ACCORD EFFERVESCENT TABLET 37.5MG/325MG	PARACETAMOL 325. mg | TRAMADOL HYDROCHLORIDE 37.5 mg	ACCORD HEALTHCARE S.L.U	15/07/2022
023737	CEFUROXIME VENUS PHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1500MG	CEFUROXIME SODIUM 1578. mg	VENUS PHARMA GMBH	16/11/2022
023736	CEFUROXIME VENUS PHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 750MG	CEFUROXIME SODIUM 789. mg	VENUS PHARMA GMBH	16/11/2022
023756	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 10000IU	ENOXAPARIN SODIUM 100. mg	VENIPHARM	16/12/2022
023752	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 2000IU	ENOXAPARIN SODIUM 20. mg	VENIPHARM	16/12/2022
023753	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 4000IU	ENOXAPARIN SODIUM 40. mg	VENIPHARM	16/12/2022
023754	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 6000IU	ENOXAPARIN SODIUM 60. mg	VENIPHARM	16/12/2022
023755	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 8000IU	ENOXAPARIN SODIUM 80. mg	VENIPHARM	16/12/2022
023615	TEKTROTYD KIT FOR RADIOPHARMACEUTICAL PREPARATION 20MCG	HYNIC-[D-PHEL1,TYR3-OCTREOTIDE]-TFA 20. µg	NARODOWE CENTRUM BADAN JADROWYCH	17/03/2022

023601	CIPROFLOXACIN VIOSER SOLUTION FOR INFUSION 2MG/ML	CIPROFLOXACIN 2. mg	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	18/02/2022
023635	LEVOFLOXACIN VIOSER SOLUTION FOR INFUSION 5MG/ML	LEVOFLOXACIN HEMIHYDRATE 5.12 mg	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	18/04/2022
023681	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 100MG	PALIPERIDONE PALMITATE 156. mg	PHARMATHEN S.A.	19/07/2022
023683	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 100MG AND 150MG	PALIPERIDONE PALMITATE 156. mg | PALIPERIDONE PALMITATE 234. mg	PHARMATHEN S.A.	19/07/2022
023682	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 150MG	PALIPERIDONE PALMITATE 234. mg	PHARMATHEN S.A.	19/07/2022
023678	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 25MG	PALIPERIDONE PALMITATE 39. mg	PHARMATHEN S.A.	19/07/2022
023679	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 50MG	PALIPERIDONE PALMITATE 78. mg	PHARMATHEN S.A.	19/07/2022
023680	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 75MG	PALIPERIDONE PALMITATE 117. mg	PHARMATHEN S.A.	19/07/2022
023654	DEXAMETHASONE/KABI SOLUTION FOR INJECTION 4MG/ML	DEXAMETHASONE SODIUM PHOSPHATE 4.37 mg	FRESENIUS KABI HELLAS A.E.	20/06/2022
023587	IBUTOMOL TABLET, FILM COATED 200MG/500MG	IBUPROFEN 200. mg | PARACETAMOL 500. mg	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	21/01/2022
023596	ODELO TABLET, FILM COATED 10MG	RIVAROXABAN 10. mg	ELPEN PHARMACEUTICAL CO INC	21/01/2022
023597	ODELO TABLET, FILM COATED 15MG	RIVAROXABAN 15. mg	ELPEN PHARMACEUTICAL CO INC	21/01/2022
023595	ODELO TABLET, FILM COATED 2.5MG	RIVAROXABAN 2.5 mg	ELPEN PHARMACEUTICAL CO INC	21/01/2022
023598	ODELO TABLET, FILM COATED 20MG	RIVAROXABAN 20. mg	ELPEN PHARMACEUTICAL CO INC	21/01/2022
023655	TEICOPLANIN APTAPHARMA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 200MG	TEICOPLANIN 200. mg	APTA MEDICA INTERNACIONAL D.O.O.	21/06/2022
023656	TEICOPLANIN APTAPHARMA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 400MG	TEICOPLANIN 400. mg	APTA MEDICA INTERNACIONAL D.O.O.	21/06/2022
023744	VALGANCICLOVIR PHARMATHEN TABLET, FILM COATED 450MG	VALGANCICLOVIR HYDROCHLORIDE 496.286 mg	PHARMATHEN S.A.	21/11/2022
023617	ABIRATERONE PHARMASCIENCE TABLET, FILM COATED 500MG	ABIRATERONE ACETATE 500. mg	PHARMASCIENCE INTERNATIONAL LTD	22/03/2022
023722	SUGAMMADEX/PHARMAZAC SOLUTION FOR INJECTION 100 MG/ML	SUGAMMADEX SODIUM 108.8 mg	PHARMAZAC S.A.	22/09/2022

023717	ZARATOR TABLET, FILM COATED 10MG	ATORVASTATIN CALCIUM 10.85 mg	UPJOHN HELLAS LTD	22/09/2022
023718	ZARATOR TABLET, FILM COATED 20MG	ATORVASTATIN CALCIUM 21.7 mg	UPJOHN HELLAS LTD	22/09/2022
023719	ZARATOR TABLET, FILM COATED 40MG	ATORVASTATIN CALCIUM 43.4 mg	UPJOHN HELLAS LTD	22/09/2022
023743	FESOTERODINE ACCORD TABLET, PROLONGED-RELEASE 4MG	FESOTERODINE FUMARATE 4. mg	ACCORD HEALTHCARE S.L.U	22/11/2022
023742	TROPICAMIDE/HEALTH-MED EYE DROPS, SOLUTION 10MG/ML	TROPICAMIDE 1. g	HEALTH-MED SP. Z O.O. SP. J.	22/11/2022
023761	AMLODIPINE/VALSARTAN/HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/160MG/12.5MG	HYDROCHLOROTHIAZIDE 12.5 mg | AMLODIPINE BESYLATE 13.888 mg | VALSARTAN 160. mg	ELPEN PHARMACEUTICAL CO INC	22/12/2022
023760	AMLODIPINE/VALSARTAN/HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 5MG/160MG/25MG	HYDROCHLOROTHIAZIDE 25. mg | AMLODIPINE BESYLATE 6.944 mg | VALSARTAN 160. mg	ELPEN PHARMACEUTICAL CO INC	22/12/2022
023758	NEBIVOLOL ACCORD TABLET 2.5MG	NEBIVOLOL HYDROCHLORIDE 2.725 mg	ACCORD HEALTHCARE S.L.U	22/12/2022
023759	NEBIVOLOL ACCORD TABLET 5MG	NEBIVOLOL HYDROCHLORIDE 5.45 mg	ACCORD HEALTHCARE S.L.U	22/12/2022
023616	CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	TRISODIUM CITRATE DIHYDRATE 40. g	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	23/02/2022
023658	MEROPENEM STERISCIENCE POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG	MEROPENEM TRIHYDRATE 1140.6 mg	STERISCIENCE B.V.	23/06/2022
023657	MEROPENEM STERISCIENCE POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG	MEROPENEM TRIHYDRATE 570.3 mg	STERISCIENCE B.V.	23/06/2022
023606	ESMOBETA SOLUTION FOR INJECTION 10MG/ML	ESMOLOL HYDROCHLORIDE 10. mg	NORIDEM ENTERPRISES LTD	24/02/2022
023621	LENALIDOMIDE STADA CAPSULE, HARD 10MG	LENALIDOMIDE 10. mg	STADA ARZNEIMITTEL AG	24/03/2022
023622	LENALIDOMIDE STADA CAPSULE, HARD 15MG	LENALIDOMIDE 15. mg	STADA ARZNEIMITTEL AG	24/03/2022

023618	LENALIDOMIDE STADA CAPSULE, HARD 2.5MG	LENALIDOMIDE 2.5 mg	STADA ARZNEIMITTEL AG	24/03/2022
023623	LENALIDOMIDE STADA CAPSULE, HARD 20MG	LENALIDOMIDE 20. mg	STADA ARZNEIMITTEL AG	24/03/2022
023624	LENALIDOMIDE STADA CAPSULE, HARD 25MG	LENALIDOMIDE 25. mg	STADA ARZNEIMITTEL AG	24/03/2022
023619	LENALIDOMIDE STADA CAPSULE, HARD 5MG	LENALIDOMIDE 5. mg	STADA ARZNEIMITTEL AG	24/03/2022
023620	LENALIDOMIDE STADA CAPSULE, HARD 7.5MG	LENALIDOMIDE 7.5 mg	STADA ARZNEIMITTEL AG	24/03/2022
023731	AZACITIDINE/STADA POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	AZACITIDINE 100. mg	STADA ARZNEIMITTEL AG	24/10/2022
023745	CABAZITAXEL FRESENIUS KABI CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	CABAZITAXEL 20. mg	FRESENIUS KABI HELLAS A.E.	25/11/2022
023661	LENALIDOMIDE NORAMEDA CAPSULE, HARD 10MG	LENALIDOMIDE 10. mg	UAB NORAMEDA	27/06/2022
023662	LENALIDOMIDE NORAMEDA CAPSULE, HARD 15MG	LENALIDOMIDE 15. mg	UAB NORAMEDA	27/06/2022
023663	LENALIDOMIDE NORAMEDA CAPSULE, HARD 25MG	LENALIDOMIDE 25. mg	UAB NORAMEDA	27/06/2022
023660	LENALIDOMIDE NORAMEDA CAPSULE, HARD 5MG	LENALIDOMIDE 5. mg	UAB NORAMEDA	27/06/2022
023747	APIXABAN WIN MEDICA TABLET, FILM COATED 2.5MG	APIXABAN 2.5 mg	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	29/11/2022
023746	APIXABAN WIN MEDICA TABLET, FILM COATED 5MG	APIXABAN 5. mg	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	29/11/2022
023696	MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INFUSION 2000MG/VIAL	MEROPENEM TRIHYDRATE 2280. mg	APTA MEDICA INTERNACIONAL D.O.O.	30/08/2022
023698	MICAFUNGIN/PHARMAZAC POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG	MICAFUNGIN SODIUM 101.73 mg	PHARMAZAC S.A.	30/08/2022
023697	MICAFUNGIN/PHARMAZAC POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 50MG	MICAFUNGIN SODIUM 50.86 mg	PHARMAZAC S.A.	30/08/2022
023592	AMLODIPINE/VALSARTAN/HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/12.5MG	VALSARTAN 160. mg | AMLODIPINE BESYLATE 13.888 mg | HYDROCHLOROTHIAZIDE 12.5 mg	GENEPHARM SA	31/01/2022
023593	AMLODIPINE/VALSARTAN/HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/25MG	HYDROCHLOROTHIAZIDE 25. mg | VALSARTAN 160. mg | AMLODIPINE BESYLATE 13.888 mg	GENEPHARM SA	31/01/2022

023594	AMLODIPINE/VALSARTAN/HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/320MG/25MG	HYDROCHLOROTHIAZIDE 25. mg | AMLODIPINE BESYLATE 13.888 mg | VALSARTAN 320. mg	GENEPHARM SA	31/01/2022
023590	AMLODIPINE/VALSARTAN/HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/12.5MG	HYDROCHLOROTHIAZIDE 12.5 mg | AMLODIPINE BESYLATE 6.944 mg | VALSARTAN 160. mg	GENEPHARM SA	31/01/2022
023591	AMLODIPINE/VALSARTAN/HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/25MG	HYDROCHLOROTHIAZIDE 25. mg | VALSARTAN 160. mg | AMLODIPINE BESYLATE 6.944 mg	GENEPHARM SA	31/01/2022
023701	IKELAN TABLET, FILM COATED 100MG	ATENOLOL 100. mg	MEDOCHEMIE LTD	31/08/2022
023699	IKELAN TABLET, FILM COATED 25MG	ATENOLOL 25. mg	MEDOCHEMIE LTD	31/08/2022
023700	IKELAN TABLET, FILM COATED 50MG	ATENOLOL 50. mg	MEDOCHEMIE LTD	31/08/2022

Αριθμός 1565

ΕΙΔΙΚΕΣ ΑΔΕΙΕΣ ΚΥΚΛΟΦΟΡΙΑΣ ΠΟΥ ΕΧΟΥΝ ΕΚΔΟΘΕΙ ΑΠΟ ΤΟ ΣΥΜΒΟΥΛΙΟ ΦΑΡΜΑΚΩΝ

Το Συμβούλιο Φαρμάκων, σύμφωνα με τις πρόνοιες του άρθρου 13Α των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμων, και σύμφωνα με τα στοιχεία που υπέβαλαν οι αιτητές, εκδίδει Ειδικές Άδειες Κυκλοφορίας Φαρμακευτικών Προϊόντων με τα πιο κάτω στοιχεία:

Αρ. Ειδικής Άδειας Κυκλοφορίας	Όνομα Φαρμακευτικού Προϊόντος	Δραστικά Συστατικά	Κάτοχος Ειδικής Άδειας Κυκλοφορίας	Ημερομηνία Έκδοσης Ειδικής Άδειας
S01262	TIMOGLAU EYE DROPS, SOLUTION 5MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	LABORATORIO EDOL - PRODUTOS FARMACEUTICOS S.A.	02/02/2022
S01264	ATOSIBAN ALTAN CONCENTRATE FOR SOLUTION FOR INFUSION 37.5MG/5ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	ALTAN PHARMACEUTICALS S.A.	07/02/2022
S01263	ATOSIBAN ALTAN SOLUTION FOR INJECTION 6.75MG/0.9ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	ALTAN PHARMACEUTICALS S.A.	07/02/2022
S01265	CARBOPLAT ONKOVIS CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	ONKOVIS GMBH	07/02/2022
S01266	GANCILEN POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	VOCATE PHARMACEUTICALS SA	11/02/2022
S01280	ADRENALINE RENAUDIN SOLUTION FOR INJECTION 1MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	LABORATOIRE RENAUDIN	16/11/2022
S01290	AFLUDITEN SOLUTION FOR INJECTION 25MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	BB PHARMA A.S.	16/11/2022
S01277	ALDOCUMAR TABLET 1MG	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	LABORATORIO ALDO-UNION S.L.	16/11/2022
S01284	ALDOCUMAR TABLET 3MG	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	LABORATORIO ALDO-UNION S.L.	16/11/2022
S01285	ALDOCUMAR TABLET 5MG	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	LABORATORIO ALDO-UNION S.L.	16/11/2022
S01288	ANIDULAFUNGIN FARMOZ POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/VIAL	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	FARMOZ-SOCIEDADE TECNICO-MEDICINAL,S.A, PORTUGAL	16/11/2022
S01278	CALCIUM CHLORIDE 10% RENAUDIN SOLUTION FOR INJECTION 1G/10ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	LABORATOIRE RENAUDIN	16/11/2022

Αρ. Ειδικής Άδειας Κυκλοφορίας	Όνομα Φαρμακευτικού Προϊόντος	Δραστικά Συστατικά	Κάτοχος Ειδικής Άδειας Κυκλοφορίας	Ημερομηνία Έκδοσης Ειδικής Άδειας
S01287	CLONIDINA ARENA TABLET 0.15MG	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	ARENA GROUP S.A.	16/11/2022
S01289	DOBUTAMINE TZF LYOPHILISATE FOR SOLUTION FOR INFUSION 250MG/VIAL	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	TARCHOMINSKIE ZAKLADY FARMACEUTYCZNE POLFA SPOLKA AKCYJNA	16/11/2022
S01279	KALII IODIDUM RAMCOPHARM TABLET 65MG	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	RAMCOPHARM LTD	16/11/2022
S01292	KANAVIT EMULSION FOR INJECTION 10MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	BB PHARMA A.S.	16/11/2022
S01283	LIDOCAINE AGUETTANT SOLUTION FOR INJECTION 10MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	SAPIENS PHARMACEUTICALS LTD	16/11/2022
S01294	MAGNESIUM SULFURICUM BBP SOLUTION FOR INJECTION OR INFUSION 200MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	BB PHARMA A.S.	16/11/2022
S01275	NEO-CANDIMYK ORAL SOLUTION 10MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	VIOFAR LTD	16/11/2022
S01293	ROBINUL SOLUTION FOR INJECTION 0.2MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	ESTEVE PHARMACEUTICALS GMBH	16/11/2022
S01286	SILVEDERMA CREAM 10MG/G	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	LABORATORIO ALDO-UNION S.L.	16/11/2022
S01291	TEICOPLANIN EBERTH POWDER FOR SOLUTION FOR INJECTION/INFUSION 400MG	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	DR. FRIEDRICH EBERTH ARZNEIMITTEL GMBH	16/11/2022
S01281	THIOLA TABLET, COATED 100MG	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	DESITIN ARZNEIMITTEL GMBH	16/11/2022
S01282	THIOLA TABLET, COATED 250MG	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	DESITIN ARZNEIMITTEL GMBH	16/11/2022
S01276	VIORIDON TABLET 10MG	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	VIOFAR LTD	16/11/2022
S01261	LITHIMOLE EYE DROPS, SOLUTION 0.5%W/V	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	COOPER SA	21/01/2022
S01272	ATROPINE SULFATE/COOPER EYE DROPS, SOLUTION 1% W/V	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	COOPER SA	21/06/2022

Αρ. Ειδικής Άδειας Κυκλοφορίας	Όνομα Φαρμακευτικού Προϊόντος	Δραστικά Συστατικά	Κάτοχος Ειδικής Άδειας Κυκλοφορίας	Ημερομηνία Έκδοσης Ειδικής Άδειας
S01273	EPHEDRINE RENAUDIN SOLUTION FOR INJECTION 30MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	LABORATOIRE RENAUDIN	21/06/2022
S01271	TRETIN GEL 0.05% W/W	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	TARGET PHARMA LTD	21/06/2022
S01274	POLIOMYELITIS VACCINE SUSPENSION FOR INJECTION	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	BILTHOVEN BIOLOGICALS B.V.	29/07/2022
S01267	INTERMED XYLOJELL SPRAY 10% W/V	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	IOULIA AND IRENE TSETI PHARMACEUTICAL LABORATORIES S.A.	30/03/2022
S01268	SIARCZAN PROTAMINY 1% SOLUTION FOR INJECTION 10MG/ML	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	WYTWORNIA SUROWIC I SZCZEPIONEK BIOMED SP. Z O.O.	30/03/2022
S01270	SODIUM BICARBONATE SOLUTION 8.4% DELTAMEDICA SOLUTION FOR INFUSION 8.4%	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	DELTAMEDICA GMBH	30/03/2022
S01269	SODIUM CHLORIDE SOLUTION 0.9% DELTAMEDICA SOLUTION FOR INJECTION 0.9%	LIDOCAINE HYDROCHLORIDE MONOHYDRATE	DELTAMEDICA GMBH	30/03/2022

Αριθμός 1566

ΑΠΟΦΑΣΕΙΣ ΓΙΑ ΑΝΑΣΤΟΛΗ/ΑΝΑΚΛΗΣΗ ΑΔΕΙΑΣ ΚΥΚΛΟΦΟΡΙΑΣ

Το Συμβούλιο Φαρμάκων, σύμφωνα με τις πρόνοιες του άρθρου 32(1) των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμων του 2001 (Ν. 70(Ι)/2001) και όπως εκάστοτε τροποποιείται, αναστέλλει/ανακαλεί τις Άδειες Κυκλοφορίας των Φαρμακευτικών Προϊόντων με τα πιο κάτω στοιχεία:

Άρ. Άδειας Κυκλοφορίας	Όνομα Φαρμακευτικού Προϊόντος	Δραστικά Συστατικά	Κάτοχος Άδειας Κυκλοφορίας	Αναστολή/Ανάκληση Άδειας Κυκλοφορίας	Ημερομηνία Αναστολής/ Ανάκλησης	Αιτιολόγηση
20656	VOLULYTE SOLUTION FOR INFUSION 6%	POLY-(O-2-HYDROXYETHL) STARCH (130/0.4), SODIUM ACETATE TRIHYDRATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MAGNESIUM CHLORIDE HEXAHYDRATE	FRESENIUS KABI DEUTSCHLAND GMBH, GERMANY	ΑΝΑΣΤΟΛΗ ΑΔΕΙΑΣ ΚΥΚΛΟΦΟΡΙΑΣ	ΑΠΟΦΑΣΗ ΣΦ: 07/09/2022	ΕΚΤΕΛΕΣΤΙΚΗ ΑΠΟΦΑΣΗ ΕΥΡΩΠΑΪΚΗΣ ΕΠΙΤΡΟΠΗΣ 24/05/2022 (C (2022) 359 final)

Αριθμός 1567

ΑΠΟΦΑΣΕΙΣ ΓΙΑ ΑΠΟΣΥΡΣΗ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΠΡΟΪΟΝΤΩΝ ΑΠΟ ΤΗΝ ΚΥΚΛΟΦΟΡΙΑ

Το Συμβούλιο Φαρμάκων, σύμφωνα με τις πρόνοιες του άρθρου 51 του περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμου του 2001 (70(Ι)/2001) όπως εκάστοτε τροποποιείται, αποφάσισε την απόσυρση των Φαρμακευτικών Προϊόντων με τα πιο κάτω στοιχεία:

Άρ. Άδειας Κυκλοφορίας	Όνομα Φαρμακευτικού Προϊόντος	Δραστικά Συστατικά	Κάτοχος Άδειας Κυκλοφορίας	Ημερομηνία Έκδοσης Άδειας	Παρτίδα απόσυρσης	Λόγος Απόσυρσης
EU/1/20/1525	JCOVDEN suspension for injection	Adenovirus Type 26 Encoding the Sars-Cov-2 Spike Glycoprotein (Ad26.Cov2-S)	Janssen-Cilag International NV	11 March 2021	XD955	Βάση του άρθρου 51.1

Αριθμός 1568

ΑΝΑΝΕΩΣΕΙΣ ΕΙΔΙΚΩΝ ΑΔΕΙΩΝ ΚΥΚΛΟΦΟΡΙΑΣ ΠΟΥ ΕΧΟΥΝ ΕΓΚΡΙΘΕΙ ΑΠΟ ΤΟ ΣΥΜΒΟΥΛΙΟ ΦΑΡΜΑΚΩΝ

Το Συμβούλιο Φαρμάκων,

- σύμφωνα με τις πρόνοιες του άρθρου 13Α των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμων του, και
- σύμφωνα με τα στοιχεία που υπέβαλαν οι αιτητές με τις αρχικές τους αιτήσεις,

ανανεώνει την ισχύ των Ειδικών Αδειών Κυκλοφορίας Φαρμακευτικών Προϊόντων με τα πιο κάτω στοιχεία:

Αρ. Ειδικής άδειας κυκλοφορίας	Όνομα φαρμακευτικού προϊόντος	Κάτοχος ειδικής άδειας κυκλοφορίας	Ισχύς άδειας
S00041	SALOSPIR TABLET, GASTRO-RESISTANT 325MG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	1/2/2022
S00264	IKOBEL EYE DROPS, SOLUTION 3MG/ML	RAFARM S.A.	29/7/2022
S00330	FLUTINASAL NASAL SPRAY, SUSPENSION 0.5MG/G	PHARMA Q S.A.	16/11/2022
S00585	MACRODANTIN CAPSULE, HARD 100MG	AMDIPHARM LIMITED	16/11/2022
S00586	APOTEL PLUS SOLUTION FOR INJECTION	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	16/11/2022
S00682	EMARFEN CAPSULE, SOFT 1MCG	MINERVA PHARMACEUTICAL SA	3/3/2022
S00692	HAEMATE P POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1000IU/VIAL	CSL BEHRING GMBH	29/7/2022
S00706	ZITHROMAX TABLET, FILM COATED 250MG	PFIZER HELLAS AE	30/3/2022
S00707	ADDAMEL N SOLUTION FOR INFUSION	FRESENIUS KABI HELLAS AE	2/2/2022
S00708	INTRALIPID EMULSION FOR INFUSION 20%	FRESENIUS KABI HELLAS AE	2/2/2022
S00709	VAMIN 14 SOLUTION FOR INFUSION	FRESENIUS KABI HELLAS AE	2/2/2022
S00710	VAMIN 18 ELECTROLYTE FREE SOLUTION FOR INFUSION	FRESENIUS KABI HELLAS AE	2/2/2022
S00711	SOLUVIT POWDER FOR SOLUTION FOR INFUSION	FRESENIUS KABI HELLAS A.E.	2/2/2022
S00712	VITALIPID INFANT EMULSION FOR INFUSION	FRESENIUS KABI HELLAS AE	2/2/2022
S00713	PEDITRACE CONCENTRATE FOR SOLUTION FOR INFUSION	FRESENIUS KABI HELLAS A.E.	2/2/2022
S00714	ISOTROIN CAPSULE, SOFT 40MG	IASIS PHARMACEUTICALS HELLAS SA	29/7/2022
S00716	NIMOTOP SOLUTION FOR INFUSION 0.2MG/ML	BAYER HELLAS ABEE	30/3/2022

S00728	RELIEF CAPSULE, HARD 4MG	IASIS PHARMACEUTICALS HELLAS SA	29/7/2022
S00729	RELIEF GEL 0.25%	IASIS PHARMACEUTICALS HELLAS SA	29/7/2022
S00730	RELIEF SOLUTION FOR INJECTION 2MG/ML	IASIS PHARMACEUTICALS HELLAS SA	29/7/2022
S00848	CROMODAL EYE DROPS, SOLUTION 40MG/ML	ZWITTER PHARMACEUTICALS LTD	16/11/2022
S00849	URPEM EYE DROPS, SOLUTION 0.25MG/ML	ZWITTER PHARMACEUTICALS LTD	16/11/2022
S00864	FYSIOFOL POWDER AND SOLVENT FOR ORAL SOLUTION	ITF HELLAS A.E.	16/11/2022
S00888	SAOCIN-D EYE OINTMENT	PHARMEX S.A.	16/11/2022
S00896	THILOCOF EYE DROPS, SOLUTION 10MG/ML	PHARMEX S.A.	16/11/2022
S00958	MECOLZINE RECTAL FOAM 1G	FAES FARMA SA	2/3/2022
S00959	POSITON CREAM	FAES FARMA SA	2/3/2022
S00966	NAFLOXIN EYE DROPS, SOLUTION 0.3%	COOPER SA	2/2/2022
S00985	FLEELAXAT ORAL SOLUTION	COOPER SA	21/6/2022
S01002	OXATREX EYE DROPS, SOLUTION 3MG/ML IN SINGLE DOSE	ZWITTER PHARMACEUTICALS LTD	2/2/2022
S01009	DAFLON TABLET, FILM COATED 500MG	LES LABORATOIRES SERVIER	29/7/2022
S01011	GYNALVEN CAPSULE, SOFT 200MG	ITF HELLAS A.E.	30/3/2022
S01012	BUVASTIN SYRUP 1.5MG/ML	COSTAKIS TSISIOS & CO. LTD	29/7/2022
S01013	TEARPROL EYE DROPS, SOLUTION (1MG/3MG)/ML	COOPER SA	30/3/2022
S01016	PROTHENOL TABLET, FILM COATED 5MG	ZWITTER PHARMACEUTICALS LTD	29/7/2022
S01025	URSOBIL CAPSULE, HARD 250MG	ABC FARMACEUTICI S P A (TORINO)ITALY	21/6/2022
S01034	T4 TABLET 12MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	16/11/2022
S01035	T4 TABLET 25MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	16/11/2022
S01078	AVOTRIN SOLUTION FOR INJECTION 20MG/ML	IOULIA AND IRENE TSETI PHARMACEUTICAL LABORATORIES S.A.	18/5/2022
S01080	HYDREASYN CAPSULE, HARD 500MG	FARMASYN S.A.	2/2/2022

S01086	WATER FOR INJECTION/VIOSER SOLVENT FOR PARENTERAL USE	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	30/3/2022
S01090	PLAQUENIL TABLET, FILM COATED 200MG	SANOFI AVENTIS AEBE	29/7/2022
S01091	AGGRAFIBAN CONCENTRATE FOR SOLUTION FOR INFUSION 0.25MG/ML	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	29/7/2022
S01112	HEMAFER SYRUP 50MG/5ML	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	1/2/2022
S01138	THYROCAP CAPSULE, HARD 37-5500 MBq	MEDIRAY GPC (G. PAPANIKOLOS - A. BOUMBAS O.E.)	2/2/2022
S01139	VITAMIN C ARENA SOLUTION FOR INJECTION 750MG/5ML	ARENA GROUP S.A.	9/2/2022
S01140	CORTINEFF TABLET 100MCG	ADAMED PHARMA S.A.	9/2/2022
S01141	FUNGUR CREAM 10MG/G	LABORATORIOS BASI - INDUSTRIA FARMACEUTICA S.A	2/2/2022
S01142	POTASSIUM CHLORIDE 10% SOLUTION FOR INTRAVENOUS INFUSION 100MG/ML	DEMO S.A.	30/3/2022
S01143	BUDESONIDE/KLEVA NASAL SPRAY, SUSPENSION 100MCG/DOSE	KLEVA PHARMACEUTICALS S.A. (TRADING AS KLEVA S.A.)	2/2/2022
S01144	COLISTIMETHATE SODIUM ALTAN PHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1MIU	ALTAN PHARMACEUTICALS S.A.	2/2/2022
S01149	FUROSEMIDE S.A.L.F. SOLUTION FOR INFUSION 250MG/25ML	S.A.L.F. S.P.A. LABORATORIO FARMACOLOGICO	21/6/2022
S01150	BIOTROPIL 1200 TABLET, FILM COATED 1200MG	BIOFARM SP. Z.O.O	21/6/2022
S01151	RESINCOLESTIRAMINA POWDER FOR ORAL SUSPENSION 4G	LABORATORIOS RUBIO, S.A.	21/6/2022
S01152	VIOTICER EAR DROPS SUSPENSION (0.2+1.0)%W/V	VERISFIELD SINGLE MEMBER S.A.	29/7/2022
S01156	ADELONE EYE DROPS, SOLUTION 10MG/ML	COOPER SA	16/11/2022
S01160	MYOCHOLINE-GLENWOOD TABLET 25MG	GLENWOOD GMBH	16/11/2022
S01162	FARMORUBICIN POWDER FOR SOLUTION FOR INJECTION 50MG/VIAL	PFIZER HELLAS AE	16/11/2022
S01163	FARMORUBICIN POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 10MG/VIAL	PFIZER HELLAS AE	16/11/2022
S01187	ULTIVA POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/VIAL	ASPEN PHARMA TRADING LIMITED	17/1/2022
S01188	ULTIVA POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/VIAL	ASPEN PHARMA TRADING LIMITED	17/1/2022
S01189	ULTIVA POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/VIAL	ASPEN PHARMA TRADING LIMITED	17/1/2022
S01192	FENEDIM GEL 1MG/G	ARITI S.A	2/2/2022

S01193	ROCURONIUM INRESA SOLUTION FOR INJECTION OR INFUSION 10MG/ML	INRESA ARZNEIMITTEL GMBH	9/2/2022
S01194	SUCRABEST GRANULES FOR ORAL SUSPENSION 1000MG/1.45G	COMBUSTIN PHARMAZEUTISCHE PRAEPARATE GMBH	2/2/2022
S01195	PANGEL GEL 50MG/G	MEDILINK PHARMACEUTICALS LTD	2/2/2022
S01196	PANGEL GEL 100MG/G	MEDILINK PHARMACEUTICALS LTD	2/2/2022
S01197	FENITOINA RUBIO SOLUTION FOR INJECTION 250MG/5ML	LABORATORIOS RUBIO, S.A.	8/2/2022
S01198	VASCAL UNO PROLONGED RELEASE CAPSULES 5MG	BIOKANOL PHARMA GMBH	9/2/2022
S01200	EPIRUBICIN AQVIDA SOLUTION FOR INJECTION 2MG/ML	AQVIDA GMBH	30/3/2022
S01201	CORTOPIN CREAM 1% W/W	PINEWOOD LABORATORIES LTD	30/3/2022
S01202	RHEOSTOP TABLET, ORODISPERSIBLE 2MG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	2/2/2022
S01205	TOBRAMYCIN SOLUTION FOR INJECTION 40MG/ML	PFIZER HELLAS AE	29/7/2022
S01206	SOLU-MEDRONE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION 125MG/VIAL	PFIZER HELLAS AE	16/11/2022
S01207	SOLU-MEDRONE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION 1000MG/VIAL	PFIZER HELLAS AE	16/11/2022
S01212	CADEN SOLUTION FOR INJECTION 6MG/2ML	PHARMA BAVARIA INTERNACIONAL (PBI) PORTUGAL UNIPESSOAL LDA.	21/6/2022
S01215	LAMIVUDINE FARMOZ TABLET, FILM COATED 300MG	FARMOZ-SOCIEDADE TECNICO-MEDICINAL, S.A, PORTUGAL	16/11/2022
S01216	PHENYLEPHRINE HYDROCHLORIDE ALTAN SOLUTION FOR INJECTION 10MG/ML	ALTAN PHARMACEUTICALS S.A.	29/7/2022
S01219	MITOMYCIN SUBSTIPHARM POWDER FOR SOLUTION FOR INJECTION/INFUSION 20MG/VIAL	SUBSTIPHARM	29/7/2022
S01220	WATER FOR INJECTION/VIOSER SOLVENT FOR PARENTERAL USE	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	29/7/2022
S01221	SODIUM CHLORIDE/VIOSER SOLUTION FOR INJECTION 0.9%	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	29/7/2022
S01222	ATROPINE/ARITI SOLUTION FOR INJECTION 1MG/ML	ARITI S.A	21/6/2022
S01223	GYNALVEN CAPSULE, SOFT 100MG	ITF HELLAS A.E.	29/7/2022
S01225	AXELOVERT NASAL SPRAY, SUSPENSION 100MCG/DOSE	PHARMEX S.A.	16/11/2022
S01226	TRIACORT SUSPENSION FOR INJECTION 40MG/1ML	SAPIENS PHARMACEUTICALS LTD	16/11/2022

Αριθμός 1569

ΑΔΕΙΕΣ ΠΑΡΑΛΛΗΛΗΣ ΕΙΣΑΓΩΓΗΣ ΠΟΥ ΕΧΟΥΝ ΕΚΔΟΘΕΙ ΑΠΟ ΤΟ ΣΥΜΒΟΥΛΙΟ ΦΑΡΜΑΚΩΝ

Το Συμβούλιο Φαρμάκων, σύμφωνα με τις πρόνοιες του άρθρου 25 των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμων, και σύμφωνα με τα στοιχεία που υπέβαλαν οι αιτητές, εκδίδει Άδεια Παράλληλης Εισαγωγής Φαρμακευτικών Προϊόντων με τα πιο κάτω στοιχεία:

Αρ. Άδειας Παράλληλης Εισαγωγής	Όνομα Φαρμακευτικού Προϊόντος	Δραστικά Συστατικά	Κάτοχος Άδειας Παράλληλης Εισαγωγής	Ημερομηνία Έκδοσης Άδειας Παράλληλης Εισαγωγής
PI0103	PANADOL COLD & FLU TABLET, FILM COATED	PSEUDOEPHEDRINE HYDROCHLORIDE 30. mg | PARACETAMOL 500. mg	FAMAR S.A .	10/2/2022
PI0103	PANADOL COLD & FLU TABLET, FILM COATED	PSEUDOEPHEDRINE HYDROCHLORIDE 30. mg | PARACETAMOL 500. mg	MARIO D. KATSIKAS S.A.	10/2/2022
PI0103	PANADOL COLD & FLU TABLET, FILM COATED	PSEUDOEPHEDRINE HYDROCHLORIDE 30. mg | PARACETAMOL 500. mg	PARAPHARM GROUP	10/2/2022
PI0103	PANADOL COLD & FLU TABLET, FILM COATED	PSEUDOEPHEDRINE HYDROCHLORIDE 30. mg | PARACETAMOL 500. mg	PHARMAFAST LTD	10/2/2022
PI0103	PANADOL COLD & FLU TABLET, FILM COATED	PSEUDOEPHEDRINE HYDROCHLORIDE 30. mg | PARACETAMOL 500. mg	PRIMEPHARM	10/2/2022
PI0104	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	ASTRAZENECA AB	4/5/2022
PI0104	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	GRUNENTHAL GMBH	4/5/2022
PI0104	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	MARIO D. KATSIKAS S.A.	4/5/2022
PI0104	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	PARAPHARM GROUP	4/5/2022
PI0104	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	PHARMAFAST LTD	4/5/2022
PI0104	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	PRIMEPHARM	4/5/2022
PI0105	TRIATEC TABLET 5MG	RAMIPRIL 5. mg	KRINERA HEALTH LTD	21/6/2022
PI0105	TRIATEC TABLET 5MG	RAMIPRIL 5. mg	LIAFARM PHARMACEUTICALS SA	21/6/2022
PI0105	TRIATEC TABLET 5MG	RAMIPRIL 5. mg	MARVIFARM S.A.	21/6/2022
PI0105	TRIATEC TABLET 5MG	RAMIPRIL 5. mg	MEDICAMERC S.A PHARMACEUTICALS	21/6/2022

PI0105	TRIATEC TABLET 5MG	RAMIPRIL 5. mg	PHARMASERVICE SA	21/6/2022
PI0105	TRIATEC TABLET 5MG	RAMIPRIL 5. mg	SANOFI S.R.L.	21/6/2022
PI0106	TRIATEC TABLET 2.5MG	RAMIPRIL 2.5 mg	KRINERA HEALTH LTD	21/6/2022
PI0106	TRIATEC TABLET 2.5MG	RAMIPRIL 2.5 mg	LIAFARM PHARMACEUTICALS SA	21/6/2022
PI0106	TRIATEC TABLET 2.5MG	RAMIPRIL 2.5 mg	MARVIFARM S.A.	21/6/2022
PI0106	TRIATEC TABLET 2.5MG	RAMIPRIL 2.5 mg	MEDICAMERC S.A PHARMACEUTICALS	21/6/2022
PI0106	TRIATEC TABLET 2.5MG	RAMIPRIL 2.5 mg	PHARMASERVICE SA	21/6/2022
PI0106	TRIATEC TABLET 2.5MG	RAMIPRIL 2.5 mg	SANOFI S.R.L.	21/6/2022
PI0107	NUROFEN EXPRESS TABLET 512MG	IBUPROFEN SODIUM DIHYDRATE 512. mg	MARIO D. KATSIKAS S.A.	21/6/2022
PI0107	NUROFEN EXPRESS TABLET 512MG	IBUPROFEN SODIUM DIHYDRATE 512. mg	PARAPHARM GROUP	21/6/2022
PI0107	NUROFEN EXPRESS TABLET 512MG	IBUPROFEN SODIUM DIHYDRATE 512. mg	PHARMAFAST LTD	21/6/2022
PI0107	NUROFEN EXPRESS TABLET 512MG	IBUPROFEN SODIUM DIHYDRATE 512. mg	PRIMEPHARM	21/6/2022
PI0107	NUROFEN EXPRESS TABLET 512MG	IBUPROFEN SODIUM DIHYDRATE 512. mg	RECKITT BENCKISER NL BRANDS B.V.	21/6/2022
PI0108	NUROFEN COLD & FLU TABLET, FILM COATED	PSEUDOEPHEDRINE HYDROCHLORIDE 30. mg | IBUPROFEN 200. mg	MARIO D. KATSIKAS S.A.	21/6/2022
PI0108	NUROFEN COLD & FLU TABLET, FILM COATED	PSEUDOEPHEDRINE HYDROCHLORIDE 30. mg | IBUPROFEN 200. mg	PARAPHARM GROUP	21/6/2022
PI0108	NUROFEN COLD & FLU TABLET, FILM COATED	PSEUDOEPHEDRINE HYDROCHLORIDE 30. mg | IBUPROFEN 200. mg	PHARMAFAST LTD	21/6/2022
PI0108	NUROFEN COLD & FLU TABLET, FILM COATED	PSEUDOEPHEDRINE HYDROCHLORIDE 30. mg | IBUPROFEN 200. mg	PRIMEPHARM	21/6/2022
PI0108	NUROFEN COLD & FLU TABLET, FILM COATED	PSEUDOEPHEDRINE HYDROCHLORIDE 30. mg | IBUPROFEN 200. mg	RECKITT BENCKISER NL BRANDS B.V.	21/6/2022
PI0109	LIPITOR TABLET, FILM COATED 20MG	ATORVASTATIN 20. mg	KRINERA HEALTH LTD	16/11/2022
PI0109	LIPITOR TABLET, FILM COATED 20MG	ATORVASTATIN 20. mg	LIAFARM PHARMACEUTICALS SA	16/11/2022
PI0109	LIPITOR TABLET, FILM COATED 20MG	ATORVASTATIN 20. mg	MARVIFARM S.A.	16/11/2022
PI0109	LIPITOR TABLET, FILM COATED 20MG	ATORVASTATIN 20. mg	MEDICAMERC S.A PHARMACEUTICALS	16/11/2022

PI0109	LIPITOR TABLET, FILM COATED 20MG	ATORVASTATIN 20. mg	PFIZER MANUFACTURING DEUTSHLAND GMBH	16/11/2022
PI0109	LIPITOR TABLET, FILM COATED 20MG	ATORVASTATIN 20. mg	PHARMASERVICE SA	16/11/2022
PI0110	LIPITOR TABLET, FILM COATED 10MG	ATORVASTATIN 10. mg	KRINERA HEALTH LTD	16/11/2022
PI0110	LIPITOR TABLET, FILM COATED 10MG	ATORVASTATIN 10. mg	LIAFARM PHARMACEUTICALS SA	16/11/2022
PI0110	LIPITOR TABLET, FILM COATED 10MG	ATORVASTATIN 10. mg	MARVIFARM S.A.	16/11/2022
PI0110	LIPITOR TABLET, FILM COATED 10MG	ATORVASTATIN 10. mg	MEDICAMERC S.A PHARMACEUTICALS	16/11/2022
PI0110	LIPITOR TABLET, FILM COATED 10MG	ATORVASTATIN 10. mg	PFIZER MANUFACTURING DEUTSHLAND GMBH	16/11/2022
PI0110	LIPITOR TABLET, FILM COATED 10MG	ATORVASTATIN 10. mg	PHARMASERVICE SA	16/11/2022
PI0111	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	GRUNENTHAL GMBH	16/11/2022
PI0111	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	KRINERA HEALTH LTD	16/11/2022
PI0111	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	LIAFARM PHARMACEUTICALS SA	16/11/2022
PI0111	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	MARVIFARM S.A.	16/11/2022
PI0111	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	MEDICAMERC S.A PHARMACEUTICALS	16/11/2022
PI0111	NEXIUM TABLET, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE 40. mg	PHARMASERVICE SA	16/11/2022

ΤΡΟΠΟΠΟΙΗΣΕΙΣ ΑΔΕΙΩΝ ΚΥΚΛΟΦΟΡΙΑΣ ΠΟΥ ΕΧΟΥΝ ΕΓΚΡΙΘΕΙ ΑΠΟ ΤΟ ΣΥΜΒΟΥΛΙΟ ΦΑΡΜΑΚΩΝ

Το Συμβούλιο Φαρμάκων, σύμφωνα με τις πρόνοιες του άρθρου 31 των περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμων του 2001 (70(I)/2001) όπως εκάστοτε τροποποιείται, ενέκρινε τις πιο κάτω τροποποιήσεις:

Ον. Φαρμακευτικού προϊόντος	Αρ. Πρωτοκόλλου	Αρ. Άδειας Κυκλο-φορίας	Κάτοχος Άδειας Κυκλοφορίας	Περιγραφή Τροποποίησης
INTRATECT SOLUTION FOR INFUSION 50G/L	8676/22T	021466	BIOTEST PHARMA GMBH	B.II.d.2.e B.II.d.2.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur.
INTRATECT SOLUTION FOR INFUSION 100G/L	8675/22T	022263	BIOTEST PHARMA GMBH	B.II.d.2.e B.II.d.2.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur.
INTRATECT SOLUTION FOR INFUSION 100G/L	8675/22T	022263	BIOTEST PHARMA GMBH	B.II.d.2.e B.II.d.2.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur.
MAINTELYTE SOLUTION FOR INFUSION 50G/L	9615/22T	023215	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RIDOCA CAPSULE, HARD 180MG	7021/22T	022134	AENORASIS SA	B.II.d.2.d B.II.d.2.d - QUALITY

				CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
RIDOCA CAPSULE, HARD 5MG	7025/22T	022130	AENORASIS SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
RIDOCA CAPSULE, HARD 140MG	7022/22T	022133	AENORASIS SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
RIDOCA CAPSULE, HARD 20MG	7024/22T	022131	AENORASIS SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
RIDOCA CAPSULE, HARD 250MG	7020/22T	022135	AENORASIS SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to

				a test procedure (including replacement or addition)
RIDOCA CAPSULE, HARD 100MG	7023/22T	022132	AENORASIS SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
BREVIBLOC SOLUTION FOR INFUSION 10MG/ML	9371/22T	023406	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ALERTAN TABLET, FILM COATED 10MG	8697/22T	020752	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ALERTAN TABLET, FILM COATED 5MG	8698/22T	020751	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	9140/22T, 9141/22T, 9142/22T, 9143/22T, 9144/22T, 9145/22T	022925	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ B.II.e.1.b.3 B.II.e.1.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Deletion of an immediate packaging contai B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in

				the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specifi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e
OCTAGAM SOLUTION FOR INFUSION 10%	9146/22T, 9147/22T, 9148/22T, 9149/22T, 9150/22T, 9151/22T	020717	OCTAPHARMA (IP) SPRL	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specifi B.II.e.1.b.3 B.II.e.1.b.3 - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Deletion of an immediate packaging contai B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ
CARAMLO TABLET 10MG/16MG	8521/22T, 8522/22T, 8523/22T	022064	ZENTIVA K.S.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.4 B.III.1.a.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - Eur B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
CARAMLO TABLET 5MG/8MG	8524/22T, 8525/22T, 8526/22T	022063	ZENTIVA K.S.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.4 B.III.1.a.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
VIGAMOX EYE DROPS, SOLUTION 5MG/ML	8551/22T	020524	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
STEROFUNDIN ISO SOLUTION FOR INFUSION	8715/22T, 8716/22T, 8717/22T, 8718/22T	021906	B. BRAUN MELSUNGEN AG	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for

				batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
VIGAMOX EYE DROPS, SOLUTION 5MG/ML	88/23T	020524	NOVARTIS IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
ZYRTEC TABLET, FILM COATED 10MG	8549/22T	013066	UCB PHARMA SA	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
ZYRTEC ORAL SOLUTION 0.1%	8550/22T	016365	UCB PHARMA SA	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or

				batch release - Not including batch control/testing
DUODART CAPSULE, HARD	8469/22T	020719	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
BIORPHEN SOLUTION FOR INJECTION OR INFUSION 0.1MG/ML	8336/22T	023255	SINTETICA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BIORPHEN SOLUTION FOR INJECTION 10MG/ML	8335/22T	023256	SINTETICA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LETYBO POWDER FOR SOLUTION FOR INJECTION 50U	8393/22T	023734	CROMA-PHARMA GMBH	B.V.a.1.z B.V.a.1.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Other variation
LETYBO POWDER FOR SOLUTION FOR INJECTION 50U	8315/22T	023734	CROMA-PHARMA GMBH	B.I.a.4.a B.I.a.4.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Tightening of in-process limits
HYDROCORTISONE ACTIVASE TABLET 10MG	6694/22T, 6695/22T	022648	ACTIVASE PHARMACEUTICALS LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
HYDROCORTISONE ACTIVASE TABLET 20MG	6692/22T, 6693/22T	022649	ACTIVASE PHARMACEUTICALS LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the

				relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BRUFEDOL TABLET, FILM COATED 600MG	1349/22T	023727	VIATRIS HEALTHCARE LIMITED.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
BRUFEDOL TABLET, FILM COATED 400MG	1350/22T	023726	VIATRIS HEALTHCARE LIMITED.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and

				conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
BRUFEDOL TABLET, FILM COATED 200MG	1351/22T	023725	VIATRIS HEALTHCARE LIMITED.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
BRUFEDOL TABLET, PROLONGED-RELEASE 800MG	1348/22T	023728	VIATRIS HEALTHCARE LIMITED.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
BENDAMUSTIN LEDPHARM POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 2.5MG/ML	8464/22T	022423	O.S.K. LEDPHARM LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared

				to the originally approved batch size
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	3204/22T	019744	SANOFI-AVENTIS GROUPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	3203/22T	019159	SANOFI-AVENTIS GROUPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	3206/22T	019160	SANOFI-AVENTIS GROUPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	3205/22T	019161	SANOFI-AVENTIS GROUPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites

				for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
YASMINELLE TABLET, FILM COATED 0.02MG/3MG	6209/22T	020125	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
YASMIN TABLET, FILM COATED 0.03MG/3MG	6210/22T	022847	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (MULTIPLE DOSES)	6218/22T	022888	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (SINGLE DOSE)	6217/22T	022887	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOGRAF SOLUTION FOR INJECTION 1.0MMOL/ML	6216/22T	023258	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	6214/22T	022534	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRIMOVIST SOLUTION FOR INJECTION IN PREFILLED SYRINGES 0.25MMOL/ML	6212/22T	019713	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of the marketing authorisation holder
QLAIRA TABLET, FILM COATED	6211/22T	020525	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOVIST PFS SOLUTION FOR INJECTION IN PREFILLED SYRINGES 1MMOL/ML	6215/22T	022535	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEBIDO SOLUTION FOR INJECTION 1000MG/4ML	6213/22T	019681	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
APLERIA TABLET, FILM COATED 50MG	8340/22T	023274	KRKA D.D. NOVO MESTO	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
APLERIA TABLET, FILM COATED 25MG	8341/22T	023273	KRKA D.D. NOVO MESTO	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
LETROZOLE TEVA TABLET, FILM COATED 2.5MG	8226/22T	021073	TEVA PHARMA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of the marketing authorisation holder
VEREGREEN OINTMENT 10%	8111/22T	021499	MEDITRINA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GEMCITABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	7863/22T	021481	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AMPICILLIN/SULBACTAM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/0.5G	9352/22T	023613	APTA MEDICA INTERNACIONAL D.O.O.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMPICILLIN/SULBACTAM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G/1G	9351/22T	023614	APTA MEDICA INTERNACIONAL D.O.O.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TANAFRA EYE DROPS, SOLUTION 50MCG/ML	5555/21T, 5556/21T	022906	PHARMATHEN S.A.	B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
LAMIVUDINE/ZIDOVUDINE ACCORD TABLET, FILM COATED 150MG/300MG	7177/22T, 7178/22T	023309	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for

				batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
TEICOPLANIN APTAPHARMA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 400MG	8039/22T	023656	APTA MEDICA INTERNACIONAL D.O.O.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TEICOPLANIN APTAPHARMA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 200MG	8040/22T	023655	APTA MEDICA INTERNACIONAL D.O.O.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product

				Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VEZIMED TABLET, FILM COATED 10MG	8109/22T	022758	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VEZIMED TABLET, FILM COATED 5MG	8110/22T	022757	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	1962/22T	023308	OCTAPHARMA (IP) SPRL	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	3009/22T	016177	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where

				relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	3011/22T	016178	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	3010/22T	018618	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 2MG	3007/22T	022006	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	3008/22T	016176	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	3012/22T	018617	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality

				control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	3962/21T	016177	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 2MG	3960/21T	022006	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	3961/21T	016176	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	3965/21T	018617	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	3963/21T	018618	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	3964/21T	016178	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	8567/22T, 8568/22T, 8569/22T, 8570/22T, 8571/22T, 8572/22T	022913	OCTAPHARMA (IP) SPRL	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active

				substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 1000IU	8561/22T, 8562/22T, 8563/22T, 8564/22T, 8565/22T, 8566/22T	022914	OCTAPHARMA (IP) SPRL	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance,

				intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ
SEROXAT TABLET, FILM COATED 20MG	3074/22T	014178	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	8366/22T	023687	TEVA PHARMA BV	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	8367/22T	023686	TEVA PHARMA BV	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved

				dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	8365/22T	023688	TEVA PHARMA BV	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	7590/22T	023687	TEVA PHARMA BV	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	7589/22T	023686	TEVA PHARMA BV	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which

				the manufacturer/importer is responsible do not include batch release
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	7591/22T	023688	TEVA PHARMA BV	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	3006/22T	016177	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	3004/22T	016178	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan -

				Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 2MG	3001/22T	022006	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	3002/22T	016176	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*

LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	3003/22T	018617	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	3005/22T	018618	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
SOOLANTRA CREAM 10MG/G	3264/22T	022320	GALDERMA INTERNATIONAL,FRANCE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SYMBICORT TURBUHALER POWDER FOR INHALATION 320MCG/9MCG	7592/22T	020882	ASTRAZENECA AB	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	7593/22T	020881	ASTRAZENECA AB	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5MCG	7571/22T	020883	ASTRAZENECA AB	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
TRIATEC PLUS TABLET 5MG/25MG	4286/22T	019071	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

				Updated certificate from an already approved manufacturer
TRIATEC TABLET 2.5MG	4288/22T	012904	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIATEC TABLET 5MG	4287/22T	012905	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

SITAGLIPTIN/MYLAN TABLET, FILM COATED 25MG	8703/22T, 8704/22T	023446	MYLAN IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
SITAGLIPTIN/MYLAN TABLET, FILM COATED 100MG	8699/22T, 8700/22T	023448	MYLAN IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing

				process of the finished product - Secondary packaging site
SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	8701/22T, 8702/22T	023447	MYLAN IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
ALLUZIENCE SOLUTION FOR INJECTION 200 SPEYWOOD UNITS/ML	6167/22T, 6168/22T, 6169/22T, 6170/22T	023486	IPSEN PHARMA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where

				relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
OCTAGAM SOLUTION FOR INFUSION 10%	5581/22T	020717	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LOCERYL MEDICATED NAIL LACQUER 5% (W/V)	7244/22T	023669	GALDERMA INTERNATIONAL,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES -

				Change in the name and/or address of the marketing authorisation holder
SOOLANTRA CREAM 10MG/G	7243/22T	022320	GALDERMA INTERNATIONAL,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EPIDUO GEL (0.001G/0.025G)G	7245/22T	022596	GALDERMA INTERNATIONAL,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SELGAMIS CREAM 50MCG/G	7246/22T	023646	GALDERMA INTERNATIONAL,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TORVACARD NEO TABLET, FILM COATED 40MG	8405/22T	022249	ZENTIVA K.S.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TORVACARD NEO TABLET, FILM COATED 80MG	8404/22T	022250	ZENTIVA K.S.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient

				(when mentioned in the dossier)*
TORVACARD NEO TABLET, FILM COATED 20MG	8406/22T	022248	ZENTIVA K.S.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TORVACARD NEO TABLET, FILM COATED 10MG	8407/22T	022247	ZENTIVA K.S.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	9083/22T	020572	MUNDIPHARMA PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	9084/22T	020571	MUNDIPHARMA PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished

				product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	9082/22T	020573	MUNDIPHARMA PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	9085/22T	020570	MUNDIPHARMA PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
FLUOROURACIL ACCORD SOLUTION FOR INJECTION OR INFUSION 50MG/ML	9012/22T	021926	ACCORD HEALTHCARE S.L.U	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
SOOLANTRA CREAM 10MG/G	7382/22T	022320	GALDERMA INTERNATIONAL,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
EPIDUO GEL (0.001G/0.025G)G	7383/22T	022596	GALDERMA INTERNATIONAL,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SELGAMIS CREAM 50MCG/G	7384/22T	023646	GALDERMA INTERNATIONAL,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
HYDROXYCHLOROQUINE SULFATE ACCORD TABLET, FILM COATED 200MG	7167/22T	023189	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
INFLUVAC SUB-UNIT TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	7115/22T	022692	MYLAN IRE HEALTHCARE LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NORADRENALINE/KABI CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	7032/22T, 7033/22T	023536	FRESENIUS KABI HELLAS AE	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GAVISCON LIQUID SACHETS	6154/22T	021163	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
VAPRESS TABLET, FILM COATED 40MG	8177/22T	021418	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

VAPRESS TABLET, FILM COATED 160MG	8175/22T	021420	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VAPRESS TABLET, FILM COATED 80MG	8176/22T	021419	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	9395/21T	020199	BAXALTA INNOVATIONS GMBH	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture -

				Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	9393/21T	020200	BAXALTA INNOVATIONS GMBH	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product

HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	9394/21T	020201	BAXALTA INNOVATIONS GMBH	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product
SINGULAIR GRANULES FOR ORAL SUSPENSION 4MG	7491/22T	019676	N.V. ORGANON	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
GLUCAGEN HYPOKIT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1MG	8560/22T	020205	NOVO NORDISK A/S	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SOLPADEINE COLD & FLU CAPSULE, HARD 500MG/100MG/6.1MG	7270/22T	023546	OMEGA PHARMA HELLAS S.A	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
SOLPADEINE COLD & FLU CAPSULE, HARD 500MG/100MG/6.1MG	7270/22T	023546	OMEGA PHARMA HELLAS S.A	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
SOLPADEINE COLD & FLU CAPSULE, HARD 500MG/100MG/6.1MG	7116/22T	023546	OMEGA PHARMA HELLAS S.A	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TIOTROPIUM/MYLAN INHALATION POWDER, HARD CAPSULE 18MCG	6787/22T	023254	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	6486/22T, 6487/22T	023120	CSL BEHRING GMBH	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent

				for a biological active substance
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	6490/22T, 6491/22T	020564	CSL BEHRING GMBH	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	6484/22T, 6485/22T	023121	CSL BEHRING GMBH	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical

				test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance
BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	6488/22T, 6489/22T	022321	CSL BEHRING GMBH	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or

				starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance
ALBUNORM 25% SOLUTION FOR INFUSION 250G/L	7117/22T, 7118/22T, 7119/22T, 7120/22T, 7121/22T, 7122/22T	020920	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the

				specifi B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
ALBUNORM 4% SOLUTION FOR INFUSION 40G/L	7129/22T, 7130/22T, 7131/22T, 7132/22T, 7133/22T, 7134/22T	020919	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the

				specifi B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
ALBUNORM 20% SOLUTION FOR INFUSION 200G/L	7123/22T, 7124/22T, 7125/22T, 7126/22T, 7127/22T, 7128/22T	020671	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the

				specifi B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
ALBUNORM 5% SOLUTION FOR INFUSION 50G/L	7135/22T, 7136/22T, 7137/22T, 7138/22T, 7139/22T, 7140/22T	020670	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the

				specifi B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU	5741/22T, 5742/22T	022208	FERRING HELLAS MEPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
MENOPUR SOLUTION FOR INJECTION IN A PRE-FILLED PEN 600IU	5739/22T, 5740/22T	023397	FERRING HELLAS MEPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material,

				reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
MENOPUR SOLUTION FOR INJECTION IN A PRE-FILLED PEN 1200IU	5737/22T, 5738/22T	023398	FERRING HELLAS MEPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
OLVION TABLET, FILM COATED 50MG	5230/22T	021291	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OLVION TABLET, FILM COATED 100MG	5231/22T	021292	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PNEUMOVAX 23 SOLUTION FOR INJECTION IN PREFILLED SYRINGES 25MCG/0.5ML	6690/22T, 6691/22T	022971	MERCK SHARP & DOHME BV	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture

				of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
ALBUNORM 25% SOLUTION FOR INFUSION 250G/L	8113/22T, 8114/22T	020920	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
ALBUNORM 4% SOLUTION FOR INFUSION 40G/L	8117/22T, 8118/22T	020919	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
ALBUNORM 20% SOLUTION FOR INFUSION 200G/L	8115/22T, 8116/22T	020671	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing

				process of the active substance - Minor change in the manufacturing process of the active substance
ALBUNORM 5% SOLUTION FOR INFUSION 50G/L	8119/22T, 8120/22T	020670	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
OLIMEL PERI N4E EMULSION FOR INFUSION	8703/21T, 8704/21T, 8705/21T, 8706/21T	022008	BAXTER (HELLAS) EPE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
OLIMEL N12E EMULSION FOR INFUSION	8691/21T, 8692/21T, 8693/21T, 8694/21T	023257	BAXTER (HELLAS) EPE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method

OLIMEL N9 EMULSION FOR INFUSION	8683/21T, 8684/21T, 8685/21T, 8686/21T	022013	BAXTER (HELLAS) EPE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
OLIMEL N9E EMULSION FOR INFUSION	8695/21T, 8696/21T, 8697/21T, 8698/21T	022011	BAXTER (HELLAS) EPE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
OLIMEL N7 EMULSION FOR INFUSION	8687/21T, 8688/21T, 8689/21T, 8690/21T	022012	BAXTER (HELLAS) EPE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification

				parameter to the specification with its corresponding test method
OLIMEL N7E EMULSION FOR INFUSION	8699/21T, 8700/21T, 8701/21T, 8702/21T	022010	BAXTER (HELLAS) EPE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
BILAZ TABLET 20MG	8511/21T, 8512/21T, 8513/21T, 8514/21T, 8515/21T, 8516/21T, 8517/21T, 8518/21T, 8519/21T, 8520/21T, 8521/21T	021475	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
NEBIDO SOLUTION FOR INJECTION 1000MG/4ML	7409/21T, 7410/21T	019681	BAYER HELLAS ABEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
VINORELBINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	6151/22T, 6152/22T	022736	ACCORD HEALTHCARE S.L.U	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
NEBIDO SOLUTION FOR INJECTION 1000MG/4ML	8362/22T	019681	BAYER HELLAS ABEE	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
WILATE 1000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	6321/22T, 6322/22T, 6323/22T, 6324/22T	021813	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specifi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e
WILATE 500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	6325/22T, 6326/22T, 6327/22T, 6328/22T	021812	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specifi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e
MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/VIAL	6274/22T	022951	APTA MEDICA INTERNACIONAL D.O.O.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	6275/22T	022950	APTA MEDICA INTERNACIONAL D.O.O.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FULVESTRANT ACCORD SOLUTION FOR INJECTION IN PREFILLED SYRINGES 250MG/5ML	6166/22T	023130	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/VIAL	7540/22T	022951	APTA MEDICA INTERNACIONAL D.O.O.	B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any

				manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products
MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	7541/22T	022950	APTA MEDICA INTERNACIONAL D.O.O.	B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products
FLUDARABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTIO 25MG/ML	6245/22T	022209	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

FULVESTRANT ACCORD SOLUTION FOR INJECTION IN PREFILLED SYRINGES 250MG/5ML	6739/22T	023130	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FOSRENOL TABLET, CHEWABLE 500MG	9132/22T	020046	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
FOSRENOL TABLET, CHEWABLE 750MG	9133/22T	020047	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	137/23T	020199	BAXALTA INNOVATIONS GMBH	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	135/23T	020201	BAXALTA INNOVATIONS GMBH	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	136/23T	020200	BAXALTA INNOVATIONS GMBH	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
TAZOCIN EF POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/VIAL	8273/22T, 8274/22T	014384	PFIZER HELLAS AE	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
LIPOPEN TABLET, FILM COATED 40MG/10MG	1674/22T	023321	ELPEN PHARMACEUTICAL CO INC	B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
LIPOPEN TABLET, FILM COATED 5MG/10MG	1671/22T	023318	ELPEN PHARMACEUTICAL CO INC	B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
LIPOPEN TABLET, FILM COATED 20MG/10MG	1673/22T	023320	ELPEN PHARMACEUTICAL CO INC	B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation

LIPOPEN TABLET, FILM COATED 10MG/10MG	1672/22T	023319	ELPEN PHARMACEUTICAL CO INC	B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
MEDOPEXOL TABLET 0.088MG	1273/22T	020555	MEDOCHEMIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
MEDOPEXOL TABLET 0.7MG	1275/22T	020557	MEDOCHEMIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
MEDOPEXOL TABLET 0.18MG	1274/22T	020556	MEDOCHEMIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process

TRIVERAM TABLET, FILM COATED 20MG/5MG/5MG	1031/22T, 1032/22T	022773	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP
TRIVERAM TABLET, FILM COATED 20MG/10MG/5MG	1033/22T, 1034/22T	022774	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP
TRIVERAM TABLET, FILM COATED 40MG/10MG/10MG	1037/22T, 1038/22T	022776	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP
TRIVERAM TABLET, FILM COATED 20MG/10MG/10MG	1035/22T, 1036/22T	022775	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP
TRIVERAM TABLET, FILM COATED 10MG/5MG/5MG	1029/22T, 1030/22T	022772	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP
DIOVAN TABLET, FILM COATED 160MG	7226/22T	019385	NOVARTIS IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
DIOVAN TABLET, FILM COATED 40MG	7228/22T	019635	NOVARTIS IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
DIOVAN TABLET, FILM COATED 80MG	7227/22T	019384	NOVARTIS IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
DIOVAN ORAL SOLUTION 3MG/ML	7225/22T	020694	NOVARTIS IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
LIPOPEN TABLET, FILM COATED 40MG/10MG	3700/22T	023321	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to

				a test procedure (including replacement or addition)
LIPOPEN TABLET, FILM COATED 5MG/10MG	3697/22T	023318	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
LIPOPEN TABLET, FILM COATED 20MG/10MG	3699/22T	023320	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
LIPOPEN TABLET, FILM COATED 10MG/10MG	3698/22T	023319	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
CO-DIOVAN TABLET, FILM COATED 80/12.5MG	8817/22T	017851	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CO-DIOVAN TABLET, FILM COATED 80/12.5MG	8817/22T	017851	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DIOVAN TABLET, FILM COATED 160MG	8815/22T	019385	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES -

				Change in the name and/or address of the marketing authorisation holder
DIOVAN TABLET, FILM COATED 160MG	8815/22T	019385	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DIOVAN TABLET, FILM COATED 40MG	8813/22T	019635	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DIOVAN TABLET, FILM COATED 40MG	8813/22T	019635	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DIOVAN TABLET, FILM COATED 80MG	8814/22T	019384	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DIOVAN TABLET, FILM COATED 80MG	8814/22T	019384	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CO-DIOVAN TABLET, FILM COATED 160/25MG	8819/22T	019477	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CO-DIOVAN TABLET, FILM COATED 160/25MG	8819/22T	019477	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CO-DIOVAN TABLET, FILM COATED 160/12.5MG	8818/22T	018977	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
CO-DIOVAN TABLET, FILM COATED 160/12.5MG	8818/22T	018977	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DIOVAN ORAL SOLUTION 3MG/ML	8816/22T	020694	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DIOVAN ORAL SOLUTION 3MG/ML	8816/22T	020694	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DIOVAN TABLET, FILM COATED 160MG	1143/22T, 1144/22T	019385	NOVARTIS IRELAND LIMITED	B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
DIOVAN TABLET, FILM COATED 40MG	1139/22T, 1140/22T	019635	NOVARTIS IRELAND LIMITED	B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change

				to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
DIOVAN TABLET, FILM COATED 80MG	1141/22T, 1142/22T	019384	NOVARTIS IRELAND LIMITED	B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
MIVIENT INHALATION POWDER, HARD CAPSULE 10MCG	9734/22T	null	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TOURAM TABLET, FILM COATED 10MG	9725/22T	023504	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
TOURAM TABLET, FILM COATED 5MG	9726/22T	023503	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NIZORAL CREAM 2%	9703/22T	011162	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZORMID EYE DROPS, SOLUTION 20MG/ML	9757/22T	022357	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
RETAFORM TABLET, PROLONGED-RELEASE 500MG	3782/22T	022981	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
RETAFORM TABLET, PROLONGED-RELEASE 750MG	3783/22T	022980	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
RETAFORM TABLET, PROLONGED-RELEASE 1000MG	3784/22T	022979	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change

				in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
RETAFORM TABLET, PROLONGED-RELEASE 500MG	4144/22T, 4145/22T, 4146/22T, 4147/22T	022981	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
RETAFORM TABLET, PROLONGED-RELEASE 750MG	4148/22T, 4149/22T, 4150/22T, 4151/22T	022980	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate

				from an already approved manufacturer
RETAFORM TABLET, PROLONGED-RELEASE 1000MG	4152/22T, 4153/22T, 4154/22T, 4155/22T	022979	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	5039/22T, 5040/22T	023032	KRKA D.D. NOVO MESTO	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release

				arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 50MG/12.5MG	5037/22T, 5038/22T	023031	KRKA D.D. NOVO MESTO	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	8373/22T	023032	KRKA D.D. NOVO MESTO	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 50MG/12.5MG	8374/22T	023031	KRKA D.D. NOVO MESTO	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LOSARTAN KRKA TABLET, FILM COATED 100MG	8369/22T	20679	KRKA D.D. NOVO MESTO	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LOSARTAN KRKA TABLET, FILM COATED 12.5MG	8372/22T	20676	KRKA D.D. NOVO MESTO	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LOSARTAN KRKA TABLET, FILM COATED 25MG	8371/22T	20677	KRKA D.D. NOVO MESTO	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LOSARTAN KRKA TABLET, FILM COATED 50MG	8370/22T	20678	KRKA D.D. NOVO MESTO	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100/12.5MG	8368/22T	020921	KRKA D.D. NOVO MESTO	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a

				new manufacturer (replacement or addition)
LOSARTAN KRKA TABLET, FILM COATED 100MG	6345/22T	20679	KRKA D.D. NOVO MESTO	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
LOSARTAN KRKA TABLET, FILM COATED 12.5MG	6348/22T	20676	KRKA D.D. NOVO MESTO	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
LOSARTAN KRKA TABLET, FILM COATED 25MG	6347/22T	20677	KRKA D.D. NOVO MESTO	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
LOSARTAN KRKA TABLET, FILM COATED 50MG	6346/22T	20678	KRKA D.D. NOVO MESTO	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
TORVACARD NEO TABLET, FILM COATED 40MG	6661/22T, 6662/22T	022249	ZENTIVA K.S.	B.II.b.4.e B.II.b.4.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - More than 10-fold

				increase compared to the originally approved batch size for immediate release (oral) pharmaceutical forms B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
TORVACARD NEO TABLET, FILM COATED 20MG	6663/22T, 6664/22T	022248	ZENTIVA K.S.	B.II.b.4.e B.II.b.4.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - More than 10-fold increase compared to the originally approved batch size for immediate release (oral) pharmaceutical forms B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
TORVACARD NEO TABLET, FILM COATED 10MG	6665/22T, 6666/22T	022247	ZENTIVA K.S.	B.II.b.4.e B.II.b.4.e - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - More than 10-fold increase compared to the originally approved batch size for immediate release (oral) pharmaceutical forms B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
TORVACARD NEO TABLET, FILM COATED 80MG	6659/22T, 6660/22T	022250	ZENTIVA K.S.	B.II.b.4.e B.II.b.4.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - More than 10-fold increase compared to the originally approved batch size for immediate release (oral) pharmaceutical forms B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor

				change in the manufacturing process
VALSARTAN KRKA TABLET, FILM COATED 80MG	6511/22T	020833	KRKA D.D. NOVO MESTO	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VALSARTAN KRKA TABLET, FILM COATED 160MG	6510/22T	020834	KRKA D.D. NOVO MESTO	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VALSARTAN KRKA TABLET, FILM COATED 40MG	6512/22T	020832	KRKA D.D. NOVO MESTO	B.III.1.a.3 B.III.1.a.3 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	6508/22T	023032	KRKA D.D. NOVO MESTO	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 50MG/12.5MG	6509/22T	023031	KRKA D.D. NOVO MESTO	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100/12.5MG	6507/22T	020921	KRKA D.D. NOVO MESTO	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
RETAFORM TABLET, PROLONGED-RELEASE 500MG	3748/22T, 3749/22T, 3750/22T, 3751/22T, 3752/22T	022981	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
RETAFORM TABLET, PROLONGED-RELEASE 750MG	3753/22T, 3754/22T, 3755/22T, 3756/22T, 3757/22T	022980	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY

				CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
RETAFORM TABLET, PROLONGED-RELEASE 1000MG	3758/22T, 3759/22T, 3760/22T, 3761/22T, 3762/22T	022979	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test

				period/storage period -
STREPFEN LOZENGE 8.75MG	9725/21T	021310	RECKITT BENCKISER HELLAS CHEMICAL ABEE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GAVISCON DOUBLE ACTION LIQUID ORAL SUSPENSION	9730/21T	022026	RECKITT BENCKISER HELLAS HEALTHCAR E SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GAVISCON DOUBLE ACTION TABLET, CHEWABLE	9729/21T	022025	RECKITT BENCKISER HELLAS HEALTHCAR E SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GAVISCON DOUBLE ACTION ORAL SUSPENSION	9728/21T	021711	RECKITT BENCKISER HELLAS HEALTHCAR E SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active

				substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
STREPFEN DIRECT HONEY & LEMON OROMUCOSAL SPRAY, SOLUTION 8.75MG	9724/21T	023399	RECKITT BENCKISER HELLAS HEALTHCAR E SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
STREPFEN ORANGE SUGAR FREE LOZENGE 8.75MG	9723/21T	021793	RECKITT BENCKISER HELLAS HEALTHCAR E SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NUROFEN EXPRESS CAPSULE, SOFT 400MG	9727/21T	021486	RECKITT BENCKISER HELLAS HEALTHCAR E SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
STREPFEN DIRECT CHERRY & MINT OROMUCOSAL SPRAY 8.75MG	9726/21T	022717	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NUROFEN FOR CHILDREN 4% ORANGE ORAL SUSPENSION 4%	7505/21T	021712	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NUROFEN FOR CHILDREN 4% STRAWBERRY ORAL SUSPENSION 4%	7504/21T	021713	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NUROFEN DURANCE MEDICATED PLASTER 200MG	7507/21T	022903	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NUROFEN LIQUID CAPSULE, SOFT 200MG	7506/21T	020918	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1200IU	8610/22T, 8611/22T	022504	FERRING HELLAS MEPE	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or

				starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 600IU	8612/22T, 8613/22T	022503	FERRING HELLAS MEPE	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU	8608/22T, 8609/22T	022208	FERRING HELLAS MEPE	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
MENOPUR SOLUTION FOR INJECTION IN A PRE-FILLED PEN 600IU	8606/22T, 8607/22T	023397	FERRING HELLAS MEPE	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
MENOPUR SOLUTION FOR INJECTION IN A PRE-FILLED PEN 1200IU	8604/22T, 8605/22T	023398	FERRING HELLAS MEPE	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
SINGULAIR TABLET, CHEWABLE 4MG	6311/22T	019291	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

SINGULAIR GRANULES FOR ORAL SUSPENSION 4MG	6312/22T	019676	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	8479/22T	019161	SANOFI-AVENTIS GROUPE	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	8480/22T	019744	SANOFI-AVENTIS GROUPE	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture

				of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	8482/22T	019159	SANOFI-AVENTIS GROUPE	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	8481/22T	019160	SANOFI-AVENTIS GROUPE	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of

				Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
BRUFEDOL TABLET, FILM COATED 600MG	6026/22T	023727	VIATRIS HEALTHCARE LIMITED.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BRUFEDOL TABLET, FILM COATED 600MG	6026/22T	023727	VIATRIS HEALTHCARE LIMITED.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
BRUFEDOL TABLET, FILM COATED 600MG	6026/22T	023727	VIATRIS HEALTHCARE LIMITED.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BRUFEDOL TABLET, FILM COATED 400MG	6027/22T	023726	VIATRIS HEALTHCARE LIMITED.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BRUFEDOL TABLET, FILM COATED 400MG	6027/22T	023726	VIATRIS HEALTHCARE LIMITED.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BRUFEDOL TABLET, FILM COATED 200MG	6028/22T	023725	VIATRIS HEALTHCARE LIMITED.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	6005/22T	019744	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	6007/22T	019159	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	6006/22T	019160	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	6004/22T	019161	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EZETIMIBE ACCORD TABLET 10MG	6208/22T	022812	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SANDIMMUN NEORAL CAPSULE, SOFT 100MG	8695/22T, 8696/22T	018383	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer

				responsible for importation and/or batch release - Not including batch control/testing
SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML	8689/22T, 8690/22T	018413	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
SANDIMMUN NEORAL CAPSULE, SOFT 25MG	8691/22T, 8692/22T	018439	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
SANDIMMUN NEORAL CAPSULE, SOFT 50MG	8693/22T, 8694/22T	018412	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of the marketing authorisation holder B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
COVERSYL TABLET, FILM COATED 10MG	997/22T, 998/22T	020031	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
COVERAM TABLET 5MG/5MG	985/22T, 986/22T	020465	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-

				significant specification parameter (e.g. deletion of an obsolete parameter)
COVERAM TABLET 5MG/10MG	987/22T, 988/22T	020466	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
PRETERAX TABLET, FILM COATED 5MG/1.25MG	1001/22T, 1002/22T	020257	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
COVERAM TABLET 10MG/5MG	989/22T, 990/22T	020467	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting

				material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
PRETERAX TABLET, FILM COATED 10MG/2.5MG	983/22T, 984/22T	20661	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
COVERSYL PLUS ARGININE TABLET, FILM COATED 2.5MG/0.625MG	999/22T, 1000/22T	020256	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
VIACORAM TABLET 3.5MG/2.5MG	971/22T, 972/22T	022642	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
TRIVERAM TABLET, FILM COATED 20MG/5MG/5MG	1005/22T, 1006/22T	022773	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
TRIVERAM TABLET, FILM COATED 20MG/10MG/5MG	1007/22T, 1008/22T	022774	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an

				obsolete parameter)
VIACORAM TABLET 7MG/5MG	973/22T, 974/22T	022643	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
COSYREL TABLET, FILM COATED 5MG/10MG	977/22T, 978/22T	022634	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
TRIVERAM TABLET, FILM COATED 40MG/10MG/10MG	1011/22T, 1012/22T	022776	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing

				process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
COSYREL TABLET, FILM COATED 10MG/5MG	979/22T, 980/22T	022635	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
COSYREL TABLET, FILM COATED 10MG/10MG	981/22T, 982/22T	022636	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
TRIVERAM TABLET, FILM COATED 20MG/10MG/10MG	1009/22T, 1010/22T	022775	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification

				parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
COSYREL TABLET, FILM COATED 5MG/5MG	975/22T, 976/22T	022633	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
TRIVERAM TABLET, FILM COATED 10MG/5MG/5MG	1003/22T, 1004/22T	022772	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
COVERAM TABLET 10MG/10MG	991/22T, 992/22T	020468	LES LABORATOI	B.I.b.1.d B.I.b.1.d - QUALITY

			RES SERVIER	CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
COVERSYL TABLET, FILM COATED 2.5MG	993/22T, 994/22T	020029	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
COVERSYL TABLET, FILM COATED 5MG	995/22T, 996/22T	020030	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant

				specification parameter (e.g. deletion of an obsolete parameter)
AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	7570/22T	020968	IPSEN PHARMA	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
SITAGLIPTIN/MYLAN TABLET, FILM COATED 25MG	5475/22T, 5476/22T, 5477/22T, 5478/22T, 5479/22T, 5480/22T	023446	MYLAN IRELAND LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the

				manufacturing proces B.II.b.4.e B.II.b.4.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - More than B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f
SITAGLIPTIN/MYLAN TABLET, FILM COATED 100MG	5463/22T, 5464/22T, 5465/22T, 5466/22T, 5467/22T, 5468/22T	023448	MYLAN IRELAND LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.4.e B.II.b.4.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - More than B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f
SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	5469/22T, 5470/22T, 5471/22T, 5472/22T, 5473/22T, 5474/22T	023447	MYLAN IRELAND LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces

				B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.4.e B.II.b.4.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - More than B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f
BILAZ TABLET, ORODISPERSIBLE 10MG	7271/21T	022833	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
BILAZ ORAL SOLUTION 2.5MG/ML	7270/21T	022853	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
BILAZ TABLET, ORODISPERSIBLE 10MG	7223/21T	022833	MENARINI INTERNATIONAL OPERATION	B.I.z B.I.z - QUALITY CHANGES - ACTIVE

			S LUXEMBOURG SA	SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
BILAZ ORAL SOLUTION 2.5MG/ML	7222/21T	022853	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
BILAZ TABLET 20MG	7269/21T	021475	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
BILAZ TABLET 20MG	7224/21T	021475	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
NOSATEL ORAL SOLUTION IN SACHET 25MG	9256/22T	023125	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
SKUDEXA TABLET, FILM COATED 75MG/25MG	9255/22T	022464	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the

				manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
NOSATEL TABLET, FILM COATED 25MG	9259/22T	020154	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
NOSATEL SOLUTION FOR INJECTION OR INFUSION 50MG/2ML	9258/22T	020155	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting

				material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
NOSATEL GRANULES FOR ORAL SOLUTION 25MG	9257/22T	022622	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
SKUDEXA GRANULES FOR ORAL SOLUTION 75MG/25MG	9254/22T	023030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in

				the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
FUNGUSTATIN CAPSULE, HARD 150MG	9561/22T	013273	PFIZER HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BILAZ TABLET 20MG	8495/22T, 8496/22T, 8497/22T	021475	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes

CERTICAN TABLET 0.25MG	7347/22T, 7348/22T, 7349/22T, 7350/22T, 7351/22T, 7352/22T	019642	NOVARTIS IRELAND LIMITED	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finis B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or

				addition of a manufacturing site for part or all of the manufacturing proces
CERTICAN TABLET 1MG	7341/22T, 7342/22T, 7343/22T, 7344/22T, 7345/22T, 7346/22T	019645	NOVARTIS IRELAND LIMITED	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finis B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.e B.II.b.1.e - QUALITY

				CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces
CERTICAN TABLET 0.5MG	7335/22T, 7336/22T, 7337/22T, 7338/22T, 7339/22T, 7340/22T	019643	NOVARTIS IRELAND LIMITED	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finis B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site

				for part or all of the manufacturing proces B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces
CERTICAN TABLET 0.75MG	7329/22T, 7330/22T, 7331/22T, 7332/22T, 7333/22T, 7334/22T	019644	NOVARTIS IRELAND LIMITED	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finis B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces
CERTICAN TABLET 0.25MG	8934/22T, 8935/22T	019642	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CERTICAN TABLET 1MG	8932/22T, 8933/22T	019645	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not

				including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CERTICAN TABLET 0.5MG	8930/22T, 8931/22T	019643	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CERTICAN TABLET 0.75MG	8928/22T, 8929/22T	019644	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

BUSCOFEM CAPSULE, SOFT 400MG	6853/22T	022424	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MUCOCOLD TABLET, FILM COATED 200MG/30MG	6851/22T	021691	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BUSCOFEM EXTRA TABLET, FILM COATED 400MG/100MG	6852/22T	023552	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SKUDEXA TABLET, FILM COATED 75MG/25MG	6349/22T, 6350/22T	022464	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority C.I.12 C.I.12 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Inclusion or deletion of black symbol and explanatory statements for medicinal products in the list of medicinal products that are subject to additional monitoring
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE	9262/22T	023760	ELPEN PHARMACEU	B.III.1.a.2 B.III.1.a.2 - QUALITY

ELPEN TABLET, FILM COATED 5MG/160MG/25MG			TICAL CO INC	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/160MG/12.5MG	9263/22T	023761	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	2715/22T, 2716/22T	020252	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.4.f B.I.a.4.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during

				the manufacture of the active substance - Addition or replacement of an in-process test as a result of a safety or quality issue B.I.b.1.e B.I.b.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a specification parameter which may have a significant effect on the overall quality of the active substance and/or the finished product
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	2717/22T, 2718/22T	017527	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.4.f B.I.a.4.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Addition or replacement of an in-process test as a result of a safety or quality issue B.I.b.1.e B.I.b.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing

				process of the active substance - Deletion of a specification parameter which may have a significant effect on the overall quality of the active substance and/or the finished product
NEBIVOLOL ACCORD TABLET 5MG	9642/22T	023759	ACCORD HEALTHCARE S.L.U	B.III.2.a.2 B.III.2.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/active substance starting material
NEBIVOLOL ACCORD TABLET 2.5MG	9641/22T	023758	ACCORD HEALTHCARE S.L.U	B.III.2.a.2 B.III.2.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/active substance starting material
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML IN PRE-FILLED SYRINGE	9057/22T	021907	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML	9059/22T	020063	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML	9058/22T	020064	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML IN PRE-FILLED SYRINGE	9056/22T	021908	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	5333/21T, 5334/21T	017527	GLAXOSMITHKLINE BIOLOGICALS SA	B.V.b.1.b B.V.b.1.b - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Referral - Update of the quality dossier intended to implement the outcome of a Union referral procedure - The harmonisation of the quality dossier was not part of the referral and the update is

				intended to harmonise it A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SMOFKABIVEN EMULSION FOR INFUSION	4007/22T, 4008/22T, 4009/22T, 4010/22T, 4011/22T	20651	FRESENIUS KABI HELLAS A.E.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
SMOFKABIVEN ELECTROLYTE FREE EMULSION FOR INFUSION	4002/22T, 4003/22T, 4004/22T, 4005/22T, 4006/22T	020716	FRESENIUS KABI HELLAS A.E.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
SMOFKABIVEN LOW OSMO PERIPHERAL EMULSION FOR INFUSION	3992/22T, 3993/22T, 3994/22T, 3995/22T, 3996/22T	023281	FRESENIUS KABI HELLAS A.E.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION	3997/22T, 3998/22T, 3999/22T, 4000/22T, 4001/22T	20667	FRESENIUS KABI HELLAS A.E.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - Eur
LEVOFLOXACIN KABI SOLUTION FOR INFUSION 5MG/ML	5860/22T	20574	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	8140/22T, 8141/22T, 8142/22T	023308	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
LEVOFLOXACIN KABI SOLUTION FOR INFUSION 5MG/ML	6204/22T	20574	FRESENIUS KABI HELLAS AE	B.II.e.7.b B.II.e.7.b - QUALITY

				CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 2000IU	8194/22T	023752	VENIPHARM	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 6000IU	8193/22T	023754	VENIPHARM	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 10000IU	8191/22T	023756	VENIPHARM	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 8000IU	8192/22T	023755	VENIPHARM	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 4000IU	8195/22T	023753	VENIPHARM	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CLOPIDOGREL ACCORD TABLET, FILM COATED 75MG	2092/21T, 2093/21T, 2094/21T	021757	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	9405/22T, 9406/22T, 9407/22T	023729	ALTAN PHARMACEUTICALS S.A.	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	8477/22T	023729	ALTAN PHARMACEUTICALS S.A.	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas
SUGAMMADEX/PHARMAZAC SOLUTION FOR INJECTION 100 MG/ML	6965/22T	023722	PHARMAZAC S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
SEPTANEST SOLUTION FOR INJECTION (40MG/5MCG)/ML	9103/22T	022513	SEPTODONT	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SEPTANEST FORTE SOLUTION FOR INJECTION (40MG/10MCG)/ML	9102/22T	022514	SEPTODONT	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FEMARA TABLET, FILM COATED 2.5MG	8832/22T	018468	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and

				quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
FEMARA TABLET, FILM COATED 2.5MG	9152/22T, 9153/22T	018468	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
MECOLZINE TABLET, GASTRO-RESISTANT 1000MG	8952/22T	023468	FAES FARMA SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a

				new manufacturer (replacement or addition)
MECOLZINE TABLET, GASTRO-RESISTANT 500MG	8953/22T	023332	FAES FARMA SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	5833/22T	016177	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	5831/22T	016178	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	5832/22T	018618	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 2MG	5835/22T	022006	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	5834/22T	016176	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible

				include batch release
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	5830/22T	018617	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
AVODART CAPSULE, SOFT 0.5MG	5762/22T	019719	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
SEROQUEL XR TABLET, PROLONGED-RELEASE 200MG	10606/20T	020357	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL XR TABLET, PROLONGED-RELEASE 50MG	10608/20T	020356	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data

SEROQUEL XR TABLET, PROLONGED-RELEASE 300MG	10602/20T	020358	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL XR TABLET, PROLONGED-RELEASE 150MG	10607/20T	020699	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL TABLET, FILM COATED 25MG	10605/20T	017716	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL TABLET, FILM COATED 100MG	10604/20T	017717	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL TABLET, FILM COATED 200MG	10603/20T	017718	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL XR TABLET, PROLONGED-RELEASE 400MG	10601/20T	020359	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VALTREX TABLET, FILM COATED 500MG	9435/21T, 9436/21T, 9437/21T	016180	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
FOSTER NEXTHALER POWDER FOR INHALATION (200MCG/12MCG)/DOSE	9237/22T	023425	CHIESI FARMACEUTICI SPA	B.III.2.b B.III.2.b - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
FOSTER NEXTHALER POWDER FOR INHALATION (200MCG/6MCG)/DOSE	9213/22T	023232	CHIESI FARMACEUTICI SPA	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
FOSTER NEXTHALER POWDER FOR INHALATION 100MCG/6MCG	9209/22T	022386	CHIESI FARMACEUTICI SPA	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
FOSTER INHALATION SOLUTION, PRESSURISED (200MCG/6MCG)/ACTUATION	7890/22T, 7891/22T, 7892/22T, 7893/22T	023294	CHIESI FARMACEUTICI SPA	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex
SINGULAIR TABLET, CHEWABLE 4MG	6956/22T	019291	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ARCOXIA TABLET, FILM COATED 90MG	6953/22T	019445	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INEGY TABLET 10MG/20MG	6960/22T	020130	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
INEGY TABLET 10MG/80MG	6962/22T	020132	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
COZAAR TABLET, FILM COATED 12.5MG	6957/22T	020464	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
REMERON TABLET, FILM COATED 30MG	6958/22T	017755	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
COZAAR TABLET, FILM COATED 50MG	6963/22T	016155	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ARCOXIA TABLET, FILM COATED 60MG	6952/22T	019444	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ARCOXIA TABLET, FILM COATED 120MG	6954/22T	019446	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INEGY TABLET 10MG/40MG	6961/22T	020131	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INEGY TABLET 10MG/10MG	6959/22T	020129	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

SINGULAIR GRANULES FOR ORAL SUSPENSION 4MG	6955/22T	019676	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FOSTER INHALATION SOLUTION, PRESSURISED 100/6 MCG/ACTUATION	7301/22T, 7302/22T, 7303/22T, 7304/22T	020440	CHIESI FARMACEUTICI SPA	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the

				finished product - Site where any manufacturing operation(s) take place, ex
ZINNAT GRANULES FOR ORAL SUSPENSION 250MG/5ML	526/22T	018086	SANDOZ PHARMACEUTICALS D.D.	B.IV.1.a.1 B.IV.1.a.1 - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking
ALLUZIENCE SOLUTION FOR INJECTION 200 SPEYWOOD UNITS/ML	1904/22T	023486	IPSEN PHARMA	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
FINASTERIDE ACCORD TABLET, FILM COATED 1MG	9769/21T, 9770/21T, 9771/21T	020815	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer,

				batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
FINASTERIDE ACCORD TABLET, FILM COATED 5MG	9772/21T, 9773/21T, 9774/21T	020816	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
RHESONATIV SOLUTION FOR INJECTION 625IU/ML	2523/22T, 2524/22T	020158	OCTAPHARMA (IP) SPRL	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference

				preparation not covered by an approved protocol
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G	6444/22T	20649	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	6445/22T	20650	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TIENAM POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	6687/22T, 6688/22T, 6689/22T	021719	MERCK SHARP & DOHME BV	A.4 A.4 - ADMINISTRATIVE CHANGES -

				Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
RENNIE DOUBLE ACTION TABLET, CHEWABLE 625MG/73.5MG/150MG	8518/22T	023471	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ASPIRIN EXPRESS TABLET, COATED 500MG	8519/22T	023554	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ASPIRIN COMPLEX COLD & FLU GRANULES FOR ORAL SUSPENSION 500MG/30MG	8520/22T	022927	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
DONEPEZIL KRKA TABLET, FILM COATED 5MG	8901/22T	021435	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
DONEPEZIL KRKA TABLET, FILM COATED 10MG	8900/22T	021436	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
RENNIE DOUBLE ACTION TABLET, CHEWABLE 625MG/73.5MG/150MG	6269/22T	023471	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RENNIE DOUBLE ACTION TABLET, CHEWABLE 625MG/73.5MG/150MG	3900/22T	023471	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ASPIRIN EXPRESS TABLET, COATED 500MG	3901/22T	023554	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	6202/22T, 6203/22T	023141	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	6200/22T, 6201/22T	023142	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	6196/22T, 6197/22T	023144	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	6198/22T, 6199/22T	023143	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SMOFLIPID EMULSION FOR INFUSION 20%	7411/22T	020184	FRESENIUS KABI HELLAS A.E.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	9625/22T	022603	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	7658/22T, 7659/22T	020573	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	7660/22T, 7661/22T	020572	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	7664/22T, 7665/22T	020570	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	7662/22T, 7663/22T	020571	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PARACETAMOL/KABI SOLUTION FOR INFUSION 10MG/ML	8504/22T	022781	FRESENIUS KABI HELLAS A.E.	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process

ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	8189/22T, 8190/22T	022345	BIOTEST PHARMA GMBH	B.V.a.1.b B.V.a.1.b - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - First-time inclusion of a new Plasma Master File not affecting the properties of the finished product B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	337/22T	022603	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NUTRIFLEX OMEGA PERI EMULSION FOR INFUSION	7928/21T, 7929/21T, 7930/21T, 7931/21T	023385	B. BRAUN MELSUNGEN AG	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.4 B.III.1.a.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product,

				packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ZOLOFT TABLET, FILM COATED 50MG	7766/22T, 7767/22T	014677	UPJOHN HELLAS LTD	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.a.4.c B.I.a.4.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Deletion of a non-significant in-process test
ZOLOFT TABLET, FILM COATED 100MG	7768/22T, 7769/22T	014678	UPJOHN HELLAS LTD	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.a.4.c B.I.a.4.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Deletion of a non-

				significant in-process test
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (4G/0.5G)/VIAL	9190/22T, 9191/22T	020530	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (2G/0.25G)/VIAL	9192/22T, 9193/22T	020529	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VESICARE ORAL SUSPENSION 1MG/ML	8602/22T	022366	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the

				name and/or address of the marketing authorisation holder
VESICARE TABLET, FILM COATED 5MG	8601/22T	019727	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VESICARE TABLET, FILM COATED 10MG	8600/22T	019751	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/10MG	9506/21T, 9507/21T	022157	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/5MG	9508/21T, 9509/21T	022158	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an

				obsolete parameter)
TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/5MG	9504/21T, 9505/21T	022156	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/10MG	9510/21T, 9511/21T	022159	LES LABORATOIRES SERVIER	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
CLARISCAN SOLUTION FOR INJECTION 0.5MMOL/ML	5787/22T	022730	GE HEALTHCARE AS	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLARISCAN SOLUTION FOR INJECTION 0.5MMOL/ML	6356/22T	022730	GE HEALTHCARE AS	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test

				period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
REMODULIN SOLUTION FOR INFUSION 1MG/ML	8280/22T, 8281/22T	020272	FERRER INTERNACIONAL S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
REMODULIN SOLUTION FOR INFUSION 2.5MG/ML	8278/22T, 8279/22T	020273	FERRER INTERNACIONAL S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in

				the dossier)* B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
REMODULIN SOLUTION FOR INFUSION 10MG/ML	8276/22T, 8277/22T	020275	FERRER INTERNACIONAL S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
REMODULIN SOLUTION FOR INFUSION 5MG/ML	8282/22T, 8283/22T	020274	FERRER INTERNACIONAL S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or

				supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
KIVIZIDIALE EYE DROPS, SOLUTION (40MCG/5MG)/ML	8603/22T	023220	BAUSCH + LOMB IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 20MG	7783/22T	018078	NOVARTIS IRELAND LIMITED	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free

SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 10MG	7784/22T	018077	NOVARTIS IRELAND LIMITED	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 30MG	7782/22T	018079	NOVARTIS IRELAND LIMITED	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active

				substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
CLARISCAN SOLUTION FOR INJECTION 0.5MMOL/ML	6675/22T, 6676/22T, 6677/22T, 6678/22T, 6679/22T, 6680/22T, 6681/22T, 6682/22T	022730	GE HEALTHCARE AS	B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc B.I.a.1.c B.I.a.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a

				starting material/reagent/intermediate used in the manufacturing process of the active substanc
NEVIRAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	8228/22T, 8229/22T	022623	ACCORD HEALTHCARE S.L.U	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
KIVIZIDIALE EYE DROPS, SOLUTION (40MCG/5MG)/ML	6122/22T, 6123/22T	023220	BAUSCH + LOMB IRELAND LIMITED	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.a B.II.e.7.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging

				components or devices (when mentioned in the dossier) - Change in the name of a supplier of a packaging component. If the information is not needed in the dossier CMDh recommends deletion of this information.
EPREX SOLUTION FOR INJECTION 40000IU/ML	9431/21T	020262	JANSSEN-CILAG INTERNATIONAL NV	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
EPREX SOLUTION FOR INJECTION 2000IU/ML	9432/21T	018279	JANSSEN-CILAG INTERNATIONAL NV	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
EPREX SOLUTION FOR INJECTION 10000IU/ML	9430/21T	018281	JANSSEN-CILAG INTERNATIONAL NV	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and

				conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
EPREX SOLUTION FOR INJECTION 4000IU/ML	9429/21T	018169	JANSSEN-CILAG INTERNATIONAL NV	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
MONTELUKAST KRKA TABLET, FILM COATED 10MG	3744/22T	023066	KRKA D.D. NOVO MESTO	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
ELIDEL CREAM 1%	null	019427	MEDA PHARMACEUTICALS S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

OLARTAN-PLUS TABLET, FILM COATED 20MG/25MG	9023/22T	020334	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLARTAN-PLUS TABLET, FILM COATED 40MG/25MG	9021/22T	021786	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	9016/22T	021495	MENARINI INTERNATIONAL OPERATIONS	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

			LUXEMBOURG SA	Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	9019/22T	021492	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLARTAN-PLUS TABLET, FILM COATED 40MG/12.5MG	9020/22T	021785	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	9015/22T	021496	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	9018/22T	021493	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ORIZAL PLUS TABLET, FILM COATED 40/10/12.5MG	9017/22T	021494	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLARTAN-PLUS TABLET, FILM COATED 20MG/12.5MG	9022/22T	020333	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LESCOL XL TABLET, PROLONGED-RELEASE 80MG	8927/22T	019110	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 125MCG/5MCG	8152/22T, 8153/22T	021396	MUNDIPHARMA PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 50MCG/5MCG	8154/22T, 8155/22T	021395	MUNDIPHARMA PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/impor

				ter is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 250MCG/10MCG	8150/22T, 8151/22T	021397	MUNDIPHARMA PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	8136/22T, 8137/22T	019691	NOVARTIS IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance,

				intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	8134/22T, 8135/22T	019692	NOVARTIS IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
LESCOL XL TABLET, PROLONGED-RELEASE 80MG	9101/22T	019110	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
NORVASC CAPSULE, HARD 5MG	6904/22T, 6905/22T	013774	UPJOHN HELLAS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting

				material/intermediate
NORVASC CAPSULE, HARD 10MG	6902/22T, 6903/22T	013775	UPJOHN HELLAS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	6371/22T	022522	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	6457/22T	022522	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ADAGREL TABLET, FILM COATED 75MG	3267/22T	20668	SAPIENS PHARMACEUTICALS LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
BUSCOFEM EXTRA TABLET, FILM COATED 400MG/100MG	4615/22T	023552	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LONATA EYE DROPS, SOLUTION (50MCG/5MG)/ML	2955/22T	023178	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CONTROLOC IV POWDER FOR SOLUTION FOR INJECTION 40MG	7298/21T, 7299/21T, 7300/21T	019298	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.d.2.e B.II.d.2.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur. B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
MIVIENT INHALATION POWDER, HARD CAPSULE 10MCG	9453/22T	null	TEVA BV	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The

				activities for which the manufacturer/importer is responsible do not include batch release
DINAPLEX CAPSULE, HARD 0.5MG/0.4MG	8483/22T	023119	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MIVIENT INHALATION POWDER, HARD CAPSULE 10MCG	1203/22T	null	TEVA BV	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
LEVOSERT INTRA UTERINE SYSTEM 52MG (20MCG/24h)	8165/21T	022402	GEDEON RICHTER PLC	B.II.e.5.z B.II.e.5.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Other variation

DIAZEPAM ACCORD TABLET 10MG	8363/22T	023467	ACCORD HEALTHCARE S.L.U	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
DIAZEPAM ACCORD TABLET 5MG	8364/22T	023466	ACCORD HEALTHCARE S.L.U	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
OLIMEL PERI N4E EMULSION FOR INFUSION	7690/21T	022008	BAXTER (HELLAS) EPE	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
OLIMEL N9E EMULSION FOR INFUSION	7692/21T	022011	BAXTER (HELLAS) EPE	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
OLIMEL N12E EMULSION FOR INFUSION	7693/21T	023257	BAXTER (HELLAS) EPE	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
OLIMEL N7E EMULSION FOR INFUSION	7691/21T	022010	BAXTER (HELLAS) EPE	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 5MG/160MG/25MG	8045/22T	023760	ELPEN PHARMACEUTICAL CO INC	B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate

				packaging of the finished product - Other changes to a test procedure (including replacement or addition)
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/160MG/25MG	8042/22T	023350	ELPEN PHARMACEUTICAL CO INC	B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/320MG/25MG	8041/22T	023351	ELPEN PHARMACEUTICAL CO INC	B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/160MG/12.5MG	8044/22T	023761	ELPEN PHARMACEUTICAL CO INC	B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 5MG/160MG/12.5MG	8043/22T	023349	ELPEN PHARMACEUTICAL CO INC	B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate

				packaging of the finished product - Other changes to a test procedure (including replacement or addition)
PANADOL COLD & FLU & COUGH POWDER FOR ORAL SOLUTION 1000MG/200MG/12.2MG	6882/22T, 6883/22T, 6884/22T	022694	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the

				active substance - Tightening of specification limits
PANADOL COLD & FLU & COUGH CAPSULE, HARD 500MG/100MG/6.1MG	6879/22T, 6880/22T, 6881/22T	022695	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits

NEVIRAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	8304/22T	022623	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
OLIMEL PERI N4E EMULSION FOR INFUSION	5293/21T	022008	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
OLIMEL N9E EMULSION FOR INFUSION	5295/21T	022011	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
OLIMEL N12E EMULSION FOR INFUSION	5296/21T	023257	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release

				in the manufacture of the finished product
OLIMEL N9 EMULSION FOR INFUSION	5298/21T	022013	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
OLIMEL N7E EMULSION FOR INFUSION	5294/21T	022010	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
OLIMEL N7 EMULSION FOR INFUSION	5297/21T	022012	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
TRAMADOL/PARACETAMOL ACCORD EFFERVESCENT TABLET 37.5MG/325MG	6620/22T	023677	ACCORD HEALTHCARE S.L.U	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the

				assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 500MG/VIAL	6505/22T	022843	SEACROSS PHARMA (EUROPE) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/VIAL	6506/22T	022842	SEACROSS PHARMA (EUROPE) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to

				be submitted by the MAH
DUCILTIA GASTRO-RESISTANT CAPSULE, HARD 60MG	1578/22T	022500	PHARMATHEN S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
DUCILTIA GASTRO-RESISTANT CAPSULE, HARD 30MG	1577/22T	022499	PHARMATHEN S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
FULVESTRANT ROMPHARM SOLUTION FOR INJECTION IN PREFILLED SYRINGES 250MG/5ML	8328/22T	023306	S.C. ROMPHARM COMPANY SRL	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
TACROLIMUS ACCORD OINTMENT 0.1%	3162/21T	023599	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal

				products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TACROLIMUS ACCORD OINTMENT 0.1%	5661/20T, 5662/20T, 5663/20T, 5664/20T, 5665/20T, 5666/20T, 5667/20T	023599	ACCORD HEALTHCARE S.L.U	B.III.1 a) 3. New certificate from a new manufacturer (replacement or addition) B.II.e.7 b) Replacement or addition of a supplier B.II.b.2 c) 1. Not including batch control/testing B.II.b.1 a) Secondary packaging site B.I.b.1 c) Addition of a new specification parameter to the specification with its corresponding test method
TACROLIMUS ACCORD OINTMENT 0.1%	3527/22T, 3528/22T, 3529/22T	023599	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
EVEROLIMUS/PHARMAZAC TABLET 5MG	4163/22T, 4164/22T, 4165/22T	023310	PHARMAZAC S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
EVEROLIMUS/PHARMAZAC TABLET 2.5MG	4160/22T, 4161/22T, 4162/22T	023302	PHARMAZAC S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
EVEROLIMUS/PHARMAZAC TABLET 10MG	4166/22T, 4167/22T, 4168/22T	023311	PHARMAZAC S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
NANOGAM SOLUTION FOR INFUSION 100MG/ML	6443/22T	023227	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
TAZOCIN EF POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/VIAL	6841/22T, 6842/22T	014384	PFIZER HELLAS AE	B.II.b.z B.II.b.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Other variation
NETENAX EYE DROPS, SOLUTION 3MG/ML	7848/22T, 7849/22T	023364	NEWLINE PHARMA, S.L.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
NETENAX EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 3MG/ML	7846/22T, 7847/22T	023365	NEWLINE PHARMA, S.L.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally

				Authorised Products
DASATINIB PHARMASCIENCE TABLET, FILM COATED 50MG	8756/22T, 8757/22T	023313	PHARMASCIENCE INTERNATIONAL LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
DASATINIB PHARMASCIENCE TABLET, FILM COATED 80MG	8752/22T, 8753/22T	023315	PHARMASCIENCE INTERNATIONAL LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance -

				Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
DASATINIB PHARMASCIENCE TABLET, FILM COATED 20MG	8758/22T, 8759/22T	023312	PHARMASCIENCE INTERNATIONAL LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
DASATINIB PHARMASCIENCE TABLET, FILM COATED 100MG	8750/22T, 8751/22T	023316	PHARMASCIENCE INTERNATIONAL LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the

				active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
DASATINIB PHARMASCIENCE TABLET, FILM COATED 140MG	8748/22T, 8749/22T	023317	PHARMASCIENCE INTERNATIONAL LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
DASATINIB PHARMASCIENCE TABLET, FILM COATED 70MG	8754/22T, 8755/22T	023314	PHARMASCIENCE INTERNATIONAL LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance -

				Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	16/22T	022399	ABBVIE PHARMACEUTICALS S.A.	C.I.6.a C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one
BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	18/22T	022401	ABBVIE PHARMACEUTICALS S.A.	C.I.6.a C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one

BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	17/22T	022400	ABBVIE PHARMACEUTICALS S.A.	C.I.6.a C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one
TRAVOCORT CREAM	2354/22T, 2355/22T, 2356/22T, 2357/22T, 2358/22T	019603	LEO PHARMA A/S	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes

				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia
TRAVOGEN CREAM 1%	2349/22T, 2350/22T, 2351/22T, 2352/22T, 2353/22T	019602	LEO PHARMA A/S	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes B.III.1.a.2 B.III.1.a.2

				- QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia
EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	7980/21T	023238	ACCORD HEALTHCARE S.L.U	B.I.z B.I.z - Quality change - Active substance - Other variation
LIOTON 1000 GEL 100000IU/100G	4606/22T	013373	A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE SRL	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
AZITHRAN INJECTABLE POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	9270/22T, 9271/22T	023712	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LOBIVON PLUS TABLET, FILM COATED 5MG/25MG	5184/22T	021789	MENARINI INTERNATIONAL OPERATION	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE

			S LUXEMBOURG SA	SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LOBIVON TABLET 5MG	5186/22T	022269	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LOBIVON PLUS TABLET, FILM COATED 5MG/12.5MG	5185/22T	021788	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	8390/22T	023143	ACCORD HEALTHCARE S.L.U	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	8392/22T	023141	ACCORD HEALTHCARE S.L.U	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	8391/22T	023142	ACCORD HEALTHCARE S.L.U	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	8389/22T	023144	ACCORD HEALTHCARE S.L.U	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

				the specification parameters and/or limits of the finished product - Other changes
AVELOX TABLET, FILM COATED 400MG	7696/22T	019636	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
YASMINELLE TABLET, FILM COATED 0.02MG/3MG	7684/22T	020125	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AVELOX SOLUTION FOR INFUSION 400MG/250ML	7697/22T	20658	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOVIST PFS SOLUTION FOR INJECTION IN PREFILLED SYRINGES 1MMOL/ML	7691/22T	022535	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (MULTIPLE DOSES)	7693/22T	022888	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (SINGLE DOSE)	7694/22T	022887	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOGRAF SOLUTION FOR INJECTION 1.0MMOL/ML	7692/22T	023258	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CIPROXIN TABLET, FILM COATED 500MG	7695/22T	011264	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	7690/22T	022534	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RENNIE DOUBLE ACTION TABLET, CHEWABLE 625MG/73.5MG/150MG	7686/22T	023471	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RENNIE DOUBLE ACTION TABLET, CHEWABLE 625MG/73.5MG/150MG	7686/22T	023471	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
QLAIRA TABLET, FILM COATED	7687/22T	020525	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
YASMIN TABLET, FILM COATED 0.03MG/3MG	7685/22T	022847	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEBIDO SOLUTION FOR INJECTION 1000MG/4ML	7689/22T	019681	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRIMOVIST SOLUTION FOR INJECTION IN PREFILLED SYRINGES 0.25MMOL/ML	7688/22T	019713	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RIASTAP POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	6639/22T, 6640/22T	021151	CSL BEHRING GMBH	B.II.b.3.c B.II.b.3.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the

				finished product, including an intermediate used in the manufacture of the finished product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits
FEBUXOSTAT RONTIS TABLET, FILM COATED 120MG	6586/22T	022646	RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FEBUXOSTAT RONTIS TABLET, FILM COATED 80MG	6587/22T	022645	RONTIS HELLAS MEDICAL AND PHARMACEUTICAL	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

			PRODUCTS S.A.	VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATAZANAVIR ACCORD CAPSULE, HARD 300MG	6022/22T, 6023/22T	023147	ACCORD HEALTHCARE S.L.U	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ATAZANAVIR ACCORD CAPSULE, HARD 150MG	6024/22T, 6025/22T	023146	ACCORD HEALTHCARE S.L.U	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ATAZANAVIR ACCORD CAPSULE, HARD 300MG	6162/22T, 6163/22T	023147	ACCORD HEALTHCARE S.L.U	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure

ATAZANAVIR ACCORD CAPSULE, HARD 150MG	6164/22T, 6165/22T	023146	ACCORD HEALTHCARE S.L.U	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	9522/22T, 9523/22T	020570	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	9518/22T, 9519/22T	020572	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	9516/22T, 9517/22T	020573	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	9520/22T, 9521/22T	020571	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
FOLIFER TABLET, FILM COATED	552/22T	020218	BIAL-PORTELA & CA, SA	B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and immediate packaging materials
IRBESARTAN ACCORD TABLET, FILM COATED 150MG	3272/22T	021645	ACCORD HEALTHCARE S.L.U	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
NEPHROTECT SOLUTION FOR INFUSION 10%	9241/22T, 9242/22T, 9243/22T, 9244/22T, 9245/22T, 9246/22T, 9247/22T	020261	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
IRBESARTAN ACCORD TABLET, FILM COATED 150MG	3389/22T, 3390/22T	021645	ACCORD HEALTHCARE S.L.U	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template) C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
ISSOFERROL TABLET, FILM COATED 90MG	8650/22T	023483	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
ISSOFERROL TABLET, FILM COATED 360MG	8648/22T	023485	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
ISSOFERROL TABLET, FILM COATED 180MG	8649/22T	023484	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
ASPIRIN FORTE TABLET, COATED 1000MG	9750/21T	023110	BAYER HELLAS ABEE	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	9649/22T, 9650/22T	020199	BAXALTA INNOVATIONS GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site

				where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	9645/22T, 9646/22T	020201	BAXALTA INNOVATIONS GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	9647/22T, 9648/22T	020200	BAXALTA INNOVATIONS GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MYOVIEW KIT FOR RADIOPHARMACEUTICAL PREPARATION 0.23MG	9138/22T	019632	GE HEALTHCARE AS (NYDALEN)	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control

				testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place
REMEDOL TABLET 500MG	9060/22T, 9061/22T, 9062/22T	019665	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
PARACETAMOL-REMEDICA TABLET 500MG	9066/22T, 9067/22T, 9068/22T	014427	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
REMEDOL FC TABLET, FILM COATED 500MG	9063/22T, 9064/22T, 9065/22T	018666	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
EVEROLIMUS/PHARMAZAC TABLET 5MG	4608/22T	023310	PHARMAZAC S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
EVEROLIMUS/PHARMAZAC TABLET 2.5MG	4609/22T	023302	PHARMAZAC S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics,

				Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
EVEROLIMUS/PHARMAZAC TABLET 10MG	4607/22T	023311	PHARMAZAC S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ALMIRAL SUPPOSITORY 100MG	9203/22T	011764	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

ALMIRAL SUPPOSITORY 50MG	9204/22T	011763	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MEDAXONUM POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	5251/22T	018561	MEDOCHE MIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
MEDAXONUM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	5252/22T	018563	MEDOCHE MIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process

MEDAXONUM POWDER FOR SOLUTION FOR INJECTION/INFUSION 250MG/VIAL	5250/22T	018562	MEDOCHEMIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
MEDAXONUM POWDER FOR SOLUTION FOR INJECTION/INFUSION 2000MG/VIAL	4871/22T	020741	MEDOCHEMIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
VORICONAZOLE/ELPEN POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	8711/22T	023082	ELPEN PHARMACEUTICAL CO INC	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

ALMIRAL TABLET, GASTRO-RESISTANT 50MG	9206/22T	009919	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ALMIRAL TABLET, GASTRO-RESISTANT 25MG	9205/22T	009918	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ESMERON SOLUTION FOR INJECTION 50MG/5ML	3594/22T	018110	MSD AFVEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
PULMOZYME NEBULISER SOLUTION 2500U/2.5ML	8809/22T, 8810/22T, 8811/22T, 8812/22T	023074	ROCHE (HELLAS) SA	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PULMOZYME NEBULISER SOLUTION 2500U/2.5ML	9080/22T	023074	ROCHE (HELLAS) SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEDISTRESS SLEEP TABLET, FILM COATED 500MG	6638/22T	022303	TILMAN S.A.	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in

				the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
METHOTREXATE ACCORD SOLUTION FOR INJECTION 25MG/ML	3789/22T, 3790/22T, 3791/22T, 3792/22T, 3793/22T, 3794/22T	021631	ACCORD HEALTHCARE S.L.U	B.II.b.4.d B.II.b.4.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finis B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation B.II.e.2.z B.II.e.2.z - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits o B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material
METHOTREXATE ACCORD SOLUTION FOR INJECTION 25MG/ML	3789/22T, 3790/22T, 3791/22T, 3792/22T, 3793/22T, 3794/22T	021631	ACCORD HEALTHCARE S.L.U	B.II.b.4.d B.II.b.4.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finis B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation B.II.e.2.z B.II.e.2.z - QUALITY

				CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits o B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material
ZYVOXID SOLUTION FOR INFUSION 2MG/ML	2566/22T	023035	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ZYVOXID TABLET, FILM COATED 600MG	2565/22T	023036	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FEMI TABLET 0.250MG/0.035MG	8284/22T	023355	ITF HELLAS A.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ANAGRELIDE AOP CAPSULE, HARD 0.5MG	5114/22T	023145	AOP ORPHAN PHARMACEUTICALS GMBH	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FLUCOZAL CAPSULE, HARD 150MG	9007/22T	019743	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LIPOCOMB CAPSULE, HARD 10MG/10MG	8594/22T, 8595/22T, 8596/22T, 8597/22T, 8598/22T	023608	EGIS PHARMACEUTICALS	B.I.d.1.c B.I.d.1.c - QUALITY CHANGES -

			PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitab B.I.c.z B.I.c.z Change of a secondary packaging component of the drug substance (including replacement or addition) B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Deletion of one manufacturing process of the active substance ma
LIPOCOMB CAPSULE, HARD 20MG/10MG	8589/22T, 8590/22T, 8591/22T, 8592/22T, 8593/22T	023609	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY	B.I.d.1.c B.I.d.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change

			(EGIS GYÓGYSZER GYÁR ZRT)	in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitab B.I.c.z B.I.c.z Change of a secondary packaging component of the drug substance (including replacement or addition) B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Deletion of one manufacturing process of the active substance ma
ORIENS VOM TABLET, SUBLINGUAL 50MG	2397/22T	022296	GALENICA SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GADOGRAF SOLUTION FOR INJECTION 1.0MMOL/ML	2661/22T	023258	BAYER HELLAS ABEE	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	2662/22T	022534	BAYER HELLAS ABEE	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
GADOVIST PFS SOLUTION FOR INJECTION IN PREFILLED SYRINGES 1MMOL/ML	2663/22T	022535	BAYER HELLAS ABEE	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	8188/22T	023276	VIATRIS HEALTHCARE LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ULTRAVIST 370 SOLUTION FOR INJECTION 76.9%	8250/21T	018966	BAYER HELLAS ABEE	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk

				management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
ULTRAVIST 300 SOLUTION FOR INJECTION 62.34%	8251/21T	023211	BAYER HELLAS ABEE	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
ZOVIDUO CREAM (50MG/10MG)/G	6738/22T	022886	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
EMTRICITABINE/TENOFOVIR DISOPROXIL SANDOZ TABLET, FILM COATED 200MG/245MG	7888/22T	022610	SANDOZ GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for

				batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GLUCOPHAGE TABLET, FILM COATED 1000MG	1207/21T	020469	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE TABLET, FILM COATED 500MG	1206/21T	020697	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 500MG	1210/21T	022947	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data

GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 1000MG	1208/21T	022949	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 750MG	1209/21T	022948	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE TABLET, FILM COATED 850MG	1211/21T	020698	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE TABLET, FILM COATED 1000MG	2724/22T	020469	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 500MG	2719/22T	022947	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 1000MG	2721/22T	022949	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 750MG	2720/22T	022948	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality,

				preclinical, clinical or pharmacovigilance data
GLUCOPHAGE TABLET, FILM COATED 850MG	2723/22T	020698	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE TABLET, FILM COATED 500MG	2722/22T	020697	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TYBETA TABLET, FILM COATED 50MG	9040/22T	022851	CODAL-SYNTO LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
TYBETA TABLET, FILM COATED 100MG	9039/22T	022852	CODAL-SYNTO LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
TYBETA TABLET, FILM COATED 25MG	9041/22T	022850	CODAL-SYNTO LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer

SALOFALK TABLET, GASTRO-RESISTANT 1G	9196/22T, 9197/22T	023177	DR. FALK PHARMA GMBH	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
ZOVIDUO CREAM (50MG/10MG)/G	7764/22T	022886	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
HEXAFLU DAY & NIGHT TABLET 500MG/60MG AND 500MG/25MG	9261/22T	023165	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
BILENI NASAL SPRAY, SUSPENSION	9100/22T	021884	MEDA PHARMACEUTICALS S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DYMISTA NASAL SPRAY, SUSPENSION	9099/22T	021885	MEDA PHARMACEUTICALS S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

ALBUREX 20 SOLUTION FOR INFUSION 200G/L	6567/22T	20630	CSL BEHRING GMBH	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes
ALBUREX 5 SOLUTION FOR INFUSION 50G/L	6568/22T	20629	CSL BEHRING GMBH	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes
BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	6984/22T	022401	ABBVIE PHARMACEUTICALS S.A.	B.II.b.4.f B.II.b.4.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line)
DEXAFREE EYE DROPS, SOLUTION 1MG/ML	5146/22T	021770	LABORATOIRES THEA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ABACAVIR ACCORD TABLET, FILM COATED 300MG	5103/22T	023264	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 5MG/100ML	8323/22T	023730	ALTAN PHARMACEUTICALS S.A.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ELIDEL CREAM 1%	643/22T	019427	MEDA PHARMACEUTICALS S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
CELECOXIB ACCORD CAPSULE, HARD 200MG	2391/22T	023492	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 300MG	5056/22T	021234	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 200MG	5057/22T	021233	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	5055/22T	021235	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 150MG	5058/22T	022451	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product -

				Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	6469/22T, 7909/22T	020570	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	6467/22T, 7907/22T	020572	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	6466/22T, 7906/22T	020573	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data

TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	6468/22T, 7908/22T	020571	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FENIVIR TINTED CREAM 1%	6782/22T	022233	OMEGA PHARMA HELLAS S.A	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	6706/21T	023688	TEVA PHARMA BV	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	6705/21T	023687	TEVA PHARMA BV	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control

				testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	6704/21T	023686	TEVA PHARMA BV	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	4648/21T	023687	TEVA PHARMA BV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	4647/21T	023686	TEVA PHARMA BV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	4649/21T	023688	TEVA PHARMA BV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
METFORMIN ACCORD TABLET, FILM COATED 850MG	4306/22T	023549	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change

				in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
METFORMIN ACCORD TABLET, FILM COATED 500MG	4307/22T	023548	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
OTRIVIN NASAL SPRAY 0.1%	7937/21T	017439	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
LAMISIL ONCE CUTANEOUS SOLUTION 1%	7938/21T	021831	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
OTRIVIN PRESERVATIVE FREE NASAL SPRAY, SOLUTION 0.1% W/V	7934/21T	022849	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/impor

			ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	ter of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
SINECOD SYRUP 0.15%	7933/21T	017781	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
OTRIVIN NASAL DROPS 0.1%	7936/21T	017436	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
OTRIVIN NASAL DROPS 0.05%	7935/21T	017437	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
FENISTIL ORAL DROPS SOLUTION 1MG/ML(=20 DROPS)	7939/21T	009662	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙ	A.5.b A.5.b - ADMINISTRATIVE CHANGES -

			ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
ZOLADEX IMPLANT 10.8MG	8914/22T	018333	ASTRAZENECA AB	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
ZOLADEX IMPLANT 3.6MG	8915/22T	013581	ASTRAZENECA AB	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance

				For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
PACLITAXEL HOSPIRA CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	8894/22T	016161	PFIZER HELLAS AE	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
DELAZO EYE DROPS, SOLUTION 20MG/ML	5527/22T, 5528/22T, 5529/22T	023180	PHARMATHEN S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate

				from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
HEMOSOL B0 SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS	8361/21T	023511	BAXTER HOLDING B.V.	B.II.f.1.e B.II.f.1.e - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change to an approved stability protocol
LEVOTHYROXINE ACCORD TABLET 50MCG	7843/22T	023139	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

LEVOTHYROXINE ACCORD TABLET 100MCG	7842/22T	023140	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LEVOTHYROXINE ACCORD TABLET 25MCG	7844/22T	023138	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZOLARAM TABLET 1MG	9265/22T	014787	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZOLARAM TABLET 0.5MG	9266/22T	019740	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZOLARAM TABLET 0.25MG	9267/22T	019739	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SERTRALINE ACCORD TABLET, FILM COATED 100MG	5020/22T	022800	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SERTRALINE ACCORD TABLET, FILM COATED 50MG	5021/22T	022799	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the

				same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VIZITRAV EYE DROPS, SOLUTION 40MCG/ML	11363/20T	023221	BAUSCH + LOMB IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CODAVAL TABLET, FILM COATED 40MG	9217/22T	021930	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CODAVAL TABLET, FILM COATED 160MG	9215/22T	021932	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CODAVAL TABLET, FILM COATED 80MG	9216/22T	021931	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MICROLAX RECTAL SOLUTION (0.45G/0.0645G/4.465G)/DOSE	8225/22T	022712	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
CLENIL FORTE INHALATION SOLUTION, PRESSURISED 250MCG/DOSE	7376/22T	012678	CHIESI HELLAS A.E.B.E.	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
DALMEVIN TABLET 50MG	6792/22T	022644	MEDOCHE MIE LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	3333/22T	022790	CSL BEHRING GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	3334/22T	022797	CSL BEHRING GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DASATINIB/TEVA TABLET, FILM COATED 20MG	8771/22T	023459	TEVA BV	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)
DASATINIB/TEVA TABLET, FILM COATED 100MG	8768/22T	023462	TEVA BV	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)
DASATINIB/TEVA TABLET, FILM COATED 70MG	8769/22T	023461	TEVA BV	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including

				replacement or addition)
DASATINIB/TEVA TABLET, FILM COATED 50MG	8770/22T	023460	TEVA BV	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)
PROKAM POWDER FOR SOLUTION FOR INJECTION 50MG	6358/22T	021674	LABORATOIRES THEA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
NALTREXONE ACCORD TABLET, FILM COATED 50MG	5693/22T	022584	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ULTIMAX TABLET, FILM COATED 400MG	7881/22T	008543	MEDOCHEMIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
ULTIMAX TABLET, FILM COATED 200MG	7882/22T	006867	MEDOCHEMIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
ULTIMAX TABLET, FILM COATED 200MG	4772/22T	006867	MEDOCHEMIE LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ULTIMAX TABLET, FILM COATED 400MG	4771/22T	008543	MEDOCHEMIE LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products

RIVAROLTO TABLET, FILM COATED 10MG	8558/22T, 8559/22T	023112	TAD PHARMA GMBH	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
RIVAROLTO TABLET, FILM COATED 15MG	8556/22T, 8557/22T	023113	TAD PHARMA GMBH	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
RIVAROLTO TABLET, FILM COATED 2.5MG	8552/22T, 8553/22T	023111	TAD PHARMA GMBH	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
RIVAROLTO TABLET, FILM COATED 20MG	8554/22T, 8555/22T	023114	TAD PHARMA GMBH	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
TIORESP INHALATION POWDER, PRE-DISPENSED 10MCG/DOSE	8581/22T	023586	ELPEN PHARMACEUTICAL CO INC	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an

				obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
PONSTAN FORTE TABLET, FILM COATED 500MG	8076/22T, 8077/22T, 8078/22T, 8079/22T, 8080/22T, 8081/22T, 8082/22T, 8083/22T, 8084/22T, 8085/22T	019500	PFIZER HELLAS AE	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monogra B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer

				(including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan
PRIMPERAN SOLUTION FOR INJECTION 10MG/2ML	4168/21T	016090	SANOFI-AVENTIS GROUPE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
PRIMPERAN TABLET 10MG	4167/21T	016093	SANOFI-AVENTIS GROUPE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LAMIVUDINE/ZIDOVUDINE ACCORD TABLET, FILM COATED 150MG/300MG	7558/21T	023309	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for

				the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
CO-DIOVAN TABLET, FILM COATED 80/12.5MG	9817/21T	017851	NOVARTIS IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CO-DIOVAN TABLET, FILM COATED 160/25MG	9819/21T	019477	NOVARTIS IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CO-DIOVAN TABLET, FILM COATED 160/12.5MG	9818/21T	018977	NOVARTIS IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

ZINNAT TABLET, FILM COATED 250MG	5006/22T, 5007/22T	016846	SANDOZ PHARMACEUTICALS D.D.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ZINNAT TABLET, FILM COATED 500MG	5004/22T, 5005/22T	016847	SANDOZ PHARMACEUTICALS D.D.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active

				substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ZINNAT GRANULES FOR ORAL SUSPENSION 250MG/5ML	5008/22T, 5009/22T	018086	SANDOZ PHARMACEUTICALS D.D.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
APIXABAN/MYLAN TABLET, FILM COATED 2.5MG	7850/22T	023469	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
APIXABAN/MYLAN TABLET, FILM COATED 5MG	7851/22T	023470	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of the marketing authorisation holder
ZINNAT TABLET, FILM COATED 250MG	9688/21T	016846	SANDOZ PHARMACEUTICALS D.D.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
FORTUM POWDER FOR SOLUTION FOR INJECTION 1G/VIAL	9693/21T	019519	SANDOZ PHARMACEUTICALS D.D.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
ZINNAT TABLET, FILM COATED 500MG	9689/21T	016847	SANDOZ PHARMACEUTICALS D.D.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a

				summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
ZINACEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 750MG	9691/21T	019521	SANDOZ PHARMACEUTICALS D.D.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
ZINNAT GRANULES FOR ORAL SUSPENSION 250MG/5ML	9690/21T	018086	SANDOZ PHARMACEUTICALS D.D.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance

				System Master File (PSMF) location
ZINACEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 1.5G	9692/21T	019520	SANDOZ PHARMACEUTICALS D.D.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
ZOVIDUO CREAM (50MG/10MG)/G	5488/22T	022886	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
PONSTAN FORTE TABLET, FILM COATED 500MG	9187/22T	019500	PFIZER HELLAS AE	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
ENTEVIREM TABLET, FILM COATED 1MG	7656/22T	022614	REMEDICA LTD	B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
ENTEVIREM TABLET, FILM COATED 0.5MG	7657/22T	022613	REMEDICA LTD	B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT -

				Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
BRIMONTAL EYE DROPS, SOLUTION 0.2% W/V	9264/22T	023061	RAFARM S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GEMCITABINE ACCORD POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	8306/22T	021356	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GEMCITABINE ACCORD POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	8305/22T	021357	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer

				responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AZEPTIL CAPSULE, HARD 500MG	9396/22T	013426	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DIAZEPAM ACCORD TABLET 10MG	7513/22T	023467	ACCORD HEALTHCARE S.L.U	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
DIAZEPAM ACCORD TABLET 5MG	7514/22T	023466	ACCORD HEALTHCARE S.L.U	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
AZEPTIL CAPSULE, HARD 500MG	9391/22T, 9392/22T	013426	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
BUFAR EASYHALER POWDER FOR INHALATION 320/9MCG/INHALATION	7085/22T	022089	ORION CORPORATION (ORION PHARMA)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LINEZOLID ACCORD SOLUTION FOR INFUSION 2MG/ML	45/22T	022785	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
IMODIUM PLUS TABLET 2MG/125MG	3709/22T	022813	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LIPTRUZET TABLET, FILM COATED 10MG/40MG	3540/22T, 3541/22T, 3542/22T, 3543/22T, 3544/22T	022098	N.V. ORGANON	B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other variation B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
LIPTRUZET TABLET, FILM COATED 10MG/20MG	3535/22T, 3536/22T, 3537/22T, 3538/22T, 3539/22T	022097	N.V. ORGANON	B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test

				procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other variation B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
LIPTRUZET TABLET, FILM COATED 10MG/80MG	3545/22T, 3546/22T, 3547/22T, 3548/22T, 3549/22T	022099	N.V. ORGANON	B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other variation B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
LIPTRUZET TABLET, FILM COATED 10MG/10MG	3530/22T, 3531/22T, 3532/22T, 3533/22T, 3534/22T	022096	N.V. ORGANON	B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other variation B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
IMODIUM PLUS TABLET 2MG/125MG	5061/22T, 5062/22T, 5063/22T, 5064/22T	022813	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PRAGIOLA CAPSULE, HARD 25MG	6886/22T	022688	KRKA D.D. NOVO MESTO	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)

PRAGIOLA CAPSULE, HARD 300MG	6888/22T	022691	KRKA D.D. NOVO MESTO	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
PRAGIOLA CAPSULE, HARD 150MG	6887/22T	022690	KRKA D.D. NOVO MESTO	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
PRAGIOLA CAPSULE, HARD 75MG	6885/22T	022689	KRKA D.D. NOVO MESTO	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
DEXAMETHASONE PHOSPHATE NORIDEM SOLUTION FOR INJECTION 4MG/ML	6824/22T, 6825/22T, 6826/22T	023415	NORIDEM ENTERPRISES LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits
MENOPUR SOLUTION FOR INJECTION IN A PRE-FILLED PEN 1200IU	5148/22T	023398	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MENOPUR SOLUTION FOR INJECTION IN A PRE-FILLED PEN 600IU	5149/22T	023397	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU	5147/22T	022208	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

MONTELUKAST KRKA TABLET, CHEWABLE 5MG	5849/22T	023065	KRKA D.D. NOVO MESTO	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MONTELUKAST KRKA TABLET, CHEWABLE 4MG	5850/22T	023064	KRKA D.D. NOVO MESTO	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MONTELUKAST KRKA TABLET, FILM COATED 10MG	5848/22T	023066	KRKA D.D. NOVO MESTO	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PROPECIA TABLET, FILM COATED 1MG	9515/22T	018318	N.V. ORGANON	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release

OTRIVIN PRESERVATIVE FREE NASAL SPRAY, SOLUTION 0.1% W/V	9464/22T	022849	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
QUETRA ORAL SOLUTION 100MG/ML	9512/22T	021968	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ALGOFEN SUPPOSITORY 250MG	8684/22T	011768	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALGOFEN SUPPOSITORY 1000MG	8683/22T	011767	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALGOFEN SUPPOSITORY 125MG	8685/22T	011766	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALGOFEN SUPPOSITORY 500MG	8686/22T	011769	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALGOFEN DUOFAST TABLET	8687/22T	019989	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZENALB 20 SOLUTION FOR INFUSION 20%	9401/22T	018839	BPL BIOPRODUC TS LABORATOR Y GMBH	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
SOLMUCOL SYRUP 20MG/ML	8103/22T, 8104/22T, 8105/22T	019527	IBSA FARMACEUT ICI ITALIA SRL	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
RAFAZIL TABLET, FILM COATED 10MG	8719/22T	020900	RAFARM S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the

				outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
RAFAZIL TABLET, FILM COATED 5MG	8720/22T	020901	RAFARM S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LONATA EYE DROPS, SOLUTION (50MCG/5MG)/ML	923/22T, 924/22T	023178	PHARMATHEN S.A.	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.b.1.z B.II.b.1.z - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes
NUROFEN DURANCE MEDICATED PLASTER 200MG	4602/22T	022903	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
RISPERDAL CONSTA POWDER & SOLVENT FOR PROLONGED RELEASE SUSPENION FOR INJECTION 37.5MG/VIAL	9079/21T	019588	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RISPERDAL CONSTA POWDER & SOLVENT FOR PROLONGED RELEASE SUSPENION FOR INJECTION 25MG/VIAL	9078/21T	019587	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RISPERDAL TABLET, FILM COATED 2MG	9082/21T	014397	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RISPERDAL TABLET, FILM COATED 4MG	9084/21T	014399	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RISPERDAL TABLET, FILM COATED 3MG	9083/21T	014398	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of the marketing authorisation holder
RISPERDAL CONSTA POWDER & SOLVENT FOR PROLONGED RELEASE SUSPENION FOR INJECTION 50MG/VIAL	9080/21T	019589	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RISPERDAL ORAL SOLUTION 1MG/ML	9085/21T	017844	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RISPERDAL TABLET, FILM COATED 1MG	9081/21T	014396	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TRIATEC PLUS TABLET 5MG/25MG	5484/22T	019071	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GLUCOPHAGE TABLET, FILM COATED 850MG	4633/22T	020698	MERCK A E HELLAS	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GLUCOPHAGE TABLET, FILM COATED 500MG	4634/22T	020697	MERCK A E HELLAS	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site

				where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GLUCOPHAGE TABLET, FILM COATED 1000MG	4632/22T	020469	MERCK A E HELLAS	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ATORVASTATIN ACCORD TABLET, FILM COATED 40MG	5052/22T	022739	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ATORVASTATIN ACCORD TABLET, FILM COATED 10MG	5054/22T	022737	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

ATORVASTATIN ACCORD TABLET, FILM COATED 20MG	5053/22T	022738	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
VERTIMED TABLET 24MG	5112/22T, 5113/22T	021298	MEDOCHEMIE LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
VERTIMED TABLET 8MG	5110/22T, 5111/22T	021296	MEDOCHEMIE LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
VERTIMED TABLET 16MG	5108/22T, 5109/22T	021297	MEDOCHEMIE LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the

				finished product - Replacement or addition of a site where batch control/testing takes place
PERSANTIN TABLET, COATED 75MG	9050/22T	003137	GLENWOOD GMBH	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
REXTOL CAPSULE, SOFT 4MCG	3306/22T	022444	RAFARM S.A.	B.I.z B.I.z - Quality change - Active substance - Other variation
REXTOL CAPSULE, SOFT 1MCG	3304/22T	022442	RAFARM S.A.	B.I.z B.I.z - Quality change - Active substance - Other variation
REXTOL CAPSULE, SOFT 2MCG	3305/22T	022443	RAFARM S.A.	B.I.z B.I.z - Quality change - Active substance - Other variation
VIDELMET TABLET, FILM COATED 50MG/850MG	6471/22T	023638	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
VIDELMET TABLET, FILM COATED 50MG/1000MG	6470/22T	023639	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ARICEPT TABLET, FILM COATED 5MG	8682/22T	017824	PFIZER HELLAS AE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ARICEPT TABLET, FILM COATED 10MG	8681/22T	017825	PFIZER HELLAS AE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REXTOL CAPSULE, SOFT 4MCG	4679/21T	022444	RAFARM S.A.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
REXTOL CAPSULE, SOFT 1MCG	4677/21T	022442	RAFARM S.A.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF

REXTOL CAPSULE, SOFT 2MCG	4678/21T	022443	RAFARM S.A.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
DELIPOST TABLET, FILM COATED 10MG	9399/22T	021915	RAFARM S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DELIPOST TABLET, FILM COATED 20MG	9398/22T	021916	RAFARM S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DELIPOST TABLET, FILM COATED 40MG	9397/22T	021917	RAFARM S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

ZYVOXID TABLET, FILM COATED 600MG	4264/22T	023036	PFIZER HELLAS AE	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
BREXIN TABLET 20MG	8618/22T	014762	CHIESI HELLAS A.E.B.E.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
NAPROREX TABLET 500MG	8577/22T	014664	DELORBIS PHARMACEUTICALS LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
NAPROREX TABLET 250MG	8578/22T	014662	DELORBIS PHARMACEUTICALS LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	4639/22T, 4640/22T	022379	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a

				- QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
YANIMO RESPIMAT SOLUTION FOR INHALATION	4637/22T, 4638/22T	022387	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
SPIRIVA RESPIMAT SOLUTION FOR INHALATION 2.5MCG/PUFF	4635/22T, 4636/22T	020301	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or

				supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 20MG	8836/22T, 8837/22T	018078	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 30MG	8834/22T, 8835/22T	018079	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for

				importation and/or batch release - Not including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 10MG	8838/22T, 8839/22T	018077	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MIDAZOLAM ACCORD SOLUTION FOR INJECTION OR INFUSION 1MG/ML	4520/22T, 4521/22T	20615	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
MIDAZOLAM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	4522/22T, 4523/22T	020616	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release

				arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
MUPIDERM OINTMENT 2% W/W	8582/22T	20603	KLEVA PHARMACEUTICALS S.A. (TRADING AS KLEVA S.A.)	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DEFEROXAMINE NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG	7250/22T, 7251/22T, 7252/22T	021179	NORIDEM ENTERPRISES LTD	B.II.b.4.d B.II.b.4.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product,

				including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
DEFEROXAMINE NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G	7247/22T, 7248/22T, 7249/22T	021180	NORIDEM ENTERPRISES LTD	B.II.b.4.d B.II.b.4.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	8783/22T	023564	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	8782/22T	023565	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	8784/22T	023563	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer

TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	8781/22T	023566	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
ACICLOVIR ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	7859/22T, 7860/22T	023226	ACCORD HEALTHCARE S.L.U	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur.

				Monograph - Updated certificate from an already approved manufacturer
FULVESTRANT ROMPHARM SOLUTION FOR INJECTION IN PREFILLED SYRINGES 250MG/5ML	8326/22T, 8327/22T	023306	S.C. ROMPHARM COMPANY SRL	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
DUSPATALIN RETARD CAPSULE, HARD, PROLONGED-RELEASE 200MG	8619/22T, 8620/22T, 8621/22T, 8622/22T, 8623/22T, 8624/22T, 8625/22T, 8626/22T, 8627/22T, 8628/22T, 8629/22T, 8630/22T, 8631/22T, 8632/22T, 8633/22T, 8634/22T, 8635/22T, 8636/22T, 8637/22T	016991	VIATRIS HEALTHCARE LIMITED.	B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active su B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.II.a.4.a B.II.a.4.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change in coating weight of oral dosage forms or change in weight of capsule shells - Solid oral pharmaceutic B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
DIOVAN TABLET, FILM COATED 80MG	7311/22T, 7312/22T	019384	NOVARTIS IRELAND LIMITED	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used

				in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
DIOVAN TABLET, FILM COATED 160MG	7309/22T, 7310/22T	019385	NOVARTIS IRELAND LIMITED	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
DIOVAN TABLET, FILM COATED 40MG	7313/22T, 7314/22T	019635	NOVARTIS IRELAND LIMITED	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used

				in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
SUGAMMADEX ANABIOSIS SOLUTION FOR INJECTION 100MG/ML	7493/22T, 7494/22T, 7495/22T, 7496/22T	023713	ANABIOSIS PC.	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance

				Master File A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use
FINGOLIMOD PHARMATHEN CAPSULE, HARD 0.5MG	2429/22T	023228	PHARMATHEN S.A.	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings
ZESTORETIC TABLET	3257/22T, 3258/22T, 3259/22T, 3260/22T, 3261/22T, 3262/22T, 3263/22T	013839	ATNAHS PHARMA NETHERLANDS B.V.	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletio B.II.b.4.b B.II.b.4.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finis B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ B.II.b.2.c.2

				B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality cont B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of
ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	5589/22T	021495	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	5592/22T	021492	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	5588/22T	021496	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of

				wording agreed by the competent authority
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	5591/22T	021493	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ORIZAL TABLET, FILM COATED 40MG/5MG	5594/22T	020613	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
ORIZAL TABLET, FILM COATED 40MG/10MG	5593/22T	020614	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ORIZAL TABLET, FILM COATED 20MG/5MG	5595/22T	020612	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

ORIZAL PLUS TABLET, FILM COATED 40/10/12.5MG	5590/22T	021494	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	8513/22T	012082	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BRUFEN TABLET, COATED 400MG	8285/22T	005754	VIATRIS HEALTHCARE LIMITED.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
INEGY TABLET 10MG/80MG	264/22T	020132	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SINGULAIR TABLET, CHEWABLE 4MG	258/22T	019291	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
COZAAR TABLET, FILM COATED 12.5MG	259/22T	020464	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites

				for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
INEGY TABLET 10MG/40MG	263/22T	020131	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
REMERON TABLET, FILM COATED 30MG	265/22T	017755	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
COZAAR TABLET, FILM COATED 50MG	260/22T	016155	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site

				where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
INEGY TABLET 10MG/10MG	261/22T	020129	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SINGULAIR GRANULES FOR ORAL SUSPENSION 4MG	257/22T	019676	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
INEGY TABLET 10MG/20MG	262/22T	020130	N.V. ORGANON	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

IMPLICOR TABLET, FILM COATED 50MG/5MG	7834/22T	022434	LES LABORATOIRES SERVIER	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
IMPLICOR TABLET, FILM COATED 50MG/7.5MG	7835/22T	022435	LES LABORATOIRES SERVIER	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
LIPTRUZET TABLET, FILM COATED 10MG/20MG	5714/22T	022097	N.V. ORGANON	B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other variation
LIPTRUZET TABLET, FILM COATED 10MG/80MG	5712/22T	022099	N.V. ORGANON	B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other variation
LIPTRUZET TABLET, FILM COATED 10MG/40MG	5713/22T	022098	N.V. ORGANON	B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test

				procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other variation
LIPTRUZET TABLET, FILM COATED 10MG/10MG	5715/22T	022096	N.V. ORGANON	B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other variation
LOMEXIN VAGINAL CAPSULE, SOFT 200MG	8467/22T, 8468/22T	022896	RECORDATI IRELAND LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Updated certificate from an already B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - New certificate for a starting mater
LOMEXIN VAGINAL CAPSULE, SOFT 600MG	8465/22T, 8466/22T	022897	RECORDATI IRELAND LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Updated certificate from an already B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - New certificate for a starting mater
BORTEZOMIB STADA SOLUTION FOR INJECTION 2.5MG/ML	7775/22T, 7776/22T	023431	STADA ARZNEIMITTEL AG	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TAVER TABLET 200MG	9272/22T	007169	MEDOCHEMIE LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
RAPIBLOC POWDER FOR SOLUTION FOR INFUSION 300MG/VIAL	2445/22T	022744	AMOMED PHARMA GMBH.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
CIPROFLOXACIN VIOSER SOLUTION FOR INFUSION 2MG/ML	3329/22T, 3330/22T	023601	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details)

				and/or changes in the Pharmacovigilance System Master File (PSMF) location
XYZAL TABLET, FILM COATED 5MG	8548/22T	020044	UCB PHARMA SA	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
XYZAL ORAL SOLUTION 0.5MG/ML	8547/22T	020127	UCB PHARMA SA	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
VALSARTAN KRKA TABLET, FILM COATED 80MG	4808/21T, 9478/21T	020833	KRKA D.D. NOVO MESTO	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority

				C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
VALSARTAN KRKA TABLET, FILM COATED 160MG	4807/21T, 9477/21T	020834	KRKA D.D. NOVO MESTO	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
VALSARTAN KRKA TABLET, FILM COATED 320MG	4805/21T, 9475/21T	020967	KRKA D.D. NOVO MESTO	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
VALSARTAN KRKA TABLET, FILM COATED 320MG	4805/21T, 9475/21T	020967	KRKA D.D. NOVO MESTO	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or

				change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
VALSARTAN KRKA TABLET, FILM COATED 40MG	4806/21T, 9476/21T	020832	KRKA D.D. NOVO MESTO	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	4143/22T	023231	BAUSCH + LOMB IRELAND LIMITED	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product

ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	9481/21T	020209	MEDOCHEMIE LTD	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	9482/21T	020210	MEDOCHEMIE LTD	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 37.5MG	9480/21T	020208	MEDOCHEMIE LTD	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and

				conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
BOSENTAN ACCORD TABLET, FILM COATED 62.5MG	6352/22T	022669	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
BOSENTAN ACCORD TABLET, FILM COATED 125MG	6351/22T	022670	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 37.5MG	7279/22T	020208	MEDOCHEMIE LTD	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	7278/22T	020209	MEDOCHEMIE LTD	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	7277/22T	020210	MEDOCHEMIE LTD	B.II.z B.II.z - QUALITY CHANGES - FINISHED

				PRODUCT - Other variation
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 37.5MG	6971/22T	020208	MEDOCHEMIE LTD	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	6970/22T	020209	MEDOCHEMIE LTD	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	6969/22T	020210	MEDOCHEMIE LTD	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
AUGMENTIN TABLET, FILM COATED 1G	8170/22T, 8171/22T, 8172/22T, 8173/22T	019515	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate /

				reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
AUGMENTIN TABLET, FILM COATED 500MG/125MG	8146/22T, 8147/22T, 8148/22T, 8149/22T	012656	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the

				active substance - Addition of a new specification parameter to the specification w B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
GEMCITABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	6649/22T	021481	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
ROSUVASTATIN+ACETYL SALICYLIC ACID/ RAFARM CAPSULE, HARD 10MG/100MG	8122/22T	023383	RAFARM S.A.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ROSUVASTATIN+ACETYL SALICYLIC ACID/ RAFARM CAPSULE, HARD 5MG/100MG	8123/22T	023382	RAFARM S.A.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ROSUVASTATIN+ACETYL SALICYLIC ACID/ RAFARM CAPSULE, HARD 20MG/100MG	8121/22T	023384	RAFARM S.A.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ELMIGRAIN TABLET, FILM COATED 40MG	7717/22T	022725	RAFARM S.A.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
OMNIC TOCAS TABLET, PROLONGED-RELEASE 0.4MG	8646/22T	022184	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TOLTERANA PROLONGED RELEASE CAPSULES 2MG	6655/22T	021911	PHARMATHEN S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOLTERANA PROLONGED RELEASE CAPSULES 4MG	6654/22T	021912	PHARMATHEN S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
GAVISCON DOUBLE ACTION ORAL SUSPENSION	2240/22T, 2241/22T	021711	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
GAVISCON DOUBLE ACTION TABLET, CHEWABLE	2181/22T, 2182/22T, 2183/22T	022025	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
SKINOREN GEL 15%	7761/21T	022916	LEO PHARMA A/S	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
TRAVOCORT CREAM	7760/21T	019603	LEO PHARMA A/S	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
TRAVOGEN CREAM 1%	7759/21T	019602	LEO PHARMA A/S	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The

				activities for which the manufacturer/importer is responsible include batch release
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 16MG/12.5MG	1898/22T	021247	KRKA D.D. NOVO MESTO	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 8MG/12.5MG	7500/22T	021246	KRKA D.D. NOVO MESTO	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/25MG	7497/22T	021249	KRKA D.D. NOVO MESTO	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 16MG/12.5MG	7499/22T	021247	KRKA D.D. NOVO MESTO	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the

				manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/12.5MG	7498/22T	021248	KRKA D.D. NOVO MESTO	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 8MG/12.5MG	2911/22T	021246	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/25MG	2913/22T	021249	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 16MG/12.5MG	2912/22T	021247	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/12.5MG	2914/22T	021248	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SEDISTRESS TABLET, COATED 200MG	8912/22T, 8913/22T	021217	TILMAN S.A.	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
ZYVOXID SOLUTION FOR INFUSION 2MG/ML	5489/22T	023035	PFIZER HELLAS AE	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Deletion of one manufacturing process of the active substance manufacturing processes
ZYVOXID TABLET, FILM COATED 600MG	5490/22T	023036	PFIZER HELLAS AE	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Deletion of one manufacturing process of the active substance manufacturing processes

DEXAMETHASONE PHOSPHATE NORIDEM SOLUTION FOR INJECTION 4MG/ML	3557/22T	023415	NORIDEM ENTERPRISES LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZOVIRAX ORAL SUSPENSION 200MG/5ML	1098/22T	010431	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
AMARYL TABLET 2MG	7323/21T	20551	SANOFI-AVENTIS GROUPE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical

				or pharmacovigilance data
AMARYL TABLET 3MG	7324/21T	20552	SANOFI-AVENTIS GROUPE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
AMARYL TABLET 4MG	7325/21T	20553	SANOFI-AVENTIS GROUPE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
AMARYL TABLET 1MG	7322/21T	020550	SANOFI-AVENTIS GROUPE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
NANOGAM SOLUTION FOR INFUSION 100MG/ML	6750/22T	023227	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
CONCERTA TABLET, PROLONGED-RELEASE 36MG	7867/22T	020340	JANSSEN-CILAG INTERNATIONAL NV	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CONCERTA TABLET, PROLONGED-RELEASE 18MG	7868/22T	020339	JANSSEN-CILAG INTERNATIONAL NV	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CONCERTA TABLET, PROLONGED-RELEASE 54MG	7866/22T	020336	JANSSEN-CILAG INTERNATIONAL NV	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VISPRING EYE DROPS 0.05%	6913/22T, 6914/22T, 6915/22T	003942	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for

				the finished product - Minor changes to an approved test procedure B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
FOLICIL TABLET 5MG	8379/22T, 8380/22T	020207	BIAL-PORTELA & CA, SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FOLIFER TABLET, FILM COATED	8377/22T, 8378/22T	020218	BIAL-PORTELA & CA, SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 150MG	4571/22T	022451	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 300MG	4569/22T	021234	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 200MG	4570/22T	021233	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place

QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	4568/22T	021235	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
MIDAZOLAM ACCORD SOLUTION FOR INJECTION OR INFUSION 1MG/ML	5160/22T	20615	ACCORD HEALTHCARE S.L.U	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
MIDAZOLAM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	5161/22T	020616	ACCORD HEALTHCARE S.L.U	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
KITONAIL MEDICATED NAIL LACQUER 80MG/G	7600/22T	021434	POLICHEM SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

STREPFEN ORANGE SUGAR FREE LOZENGE 8.75MG	4312/22T	021793	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
AXETINE TABLET, FILM COATED 500MG	9136/22T	020763	MEDOCHEMIE LTD	B.II.a.z B.II.a.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Other variation
AXETINE TABLET, FILM COATED 250MG	9137/22T	020762	MEDOCHEMIE LTD	B.II.a.z B.II.a.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Other variation
DEFERASIROX MSN TABLET, FILM COATED 360MG	8166/22T	023424	MSN LABS EUROPE LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DEFERASIROX MSN TABLET, FILM COATED 90MG	8168/22T	023422	MSN LABS EUROPE LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a

				generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DEFERASIROX MSN TABLET, FILM COATED 180MG	8167/22T	023423	MSN LABS EUROPE LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
IBUTOMOL TABLET, FILM COATED 200MG/500MG	3937/22T	023587	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment,

				e.g. translations are not yet agreed upon C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PRIMAQUINE TABLET, FILM COATED 7.5MG	9097/22T	012368	REMEDICA LTD	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
GRAFALON CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	9088/22T	017186	NEOVII BIOTECH GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or

				supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
KANILAD TABLET, FILM COATED 100MG	8095/22T	022714	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
KANILAD TABLET, FILM COATED 150MG	8094/22T	022715	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of

				wording agreed by the competent authority
KANILAD TABLET, FILM COATED 50MG	8096/22T	022713	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
KANILAD TABLET, FILM COATED 200MG	8093/22T	022716	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 200MCG	9011/22T	019505	NOVARTIS IRELAND LIMITED	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 400MCG	9010/22T	019506	NOVARTIS IRELAND LIMITED	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ESRAN TABLET 800MG	4967/22T	023494	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
NEXIUM GASTRO-RESISTANT GRANULES FOR ORAL SUSPENSION 10MG	8385/21T, 8386/21T, 8387/21T	020461	C G PAPALOISOU LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G	7857/22T	20649	FRESENIUS KABI HELLAS AE	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is

				used in the last steps of the synthesis and the material is not claimed to be endotoxin free
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	7858/22T	20650	FRESENIUS KABI HELLAS AE	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
SEROXAT TABLET, FILM COATED 20MG	5743/22T	014178	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	5024/22T	019080	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of the marketing authorisation holder
PROGRAF CAPSULE, HARD 5MG	5026/22T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PROGRAF CAPSULE, HARD 1MG	5025/22T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PROGRAF CAPSULE, HARD 0.5MG	5027/22T	022365	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ISSOFERROL TABLET, FILM COATED 90MG	2517/22T	023483	ELPEN PHARMACEUTICAL CO INC	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ISSOFERROL TABLET, FILM COATED 360MG	2519/22T	023485	ELPEN PHARMACEUTICAL CO INC	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ISSOFERROL TABLET, FILM COATED 180MG	2518/22T	023484	ELPEN PHARMACEUTICAL CO INC	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
TIORESP INHALATION POWDER, PRE-DISPENSED 10MCG/DOSE	7856/22T	023586	ELPEN PHARMACEUTICAL CO INC	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
REMEDIUM TABLET 5MG	4035/22T, 4036/22T, 4037/22T	007750	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE

				CHANGES - Change in name of the active substance or of an excipient B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NOSATEL TABLET, FILM COATED 25MG	3785/22T, 3786/22T	020154	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product
MODIODAL TABLET 100MG	6589/22T	018944	TEVA BV	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
OTRIVIN PRESERVATIVE FREE NASAL SPRAY, SOLUTION 0.1% W/V	9317/22T, 9318/22T, 9319/22T, 9320/22T	022849	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
BALANCE 4.25% GLUCOSE, 1.25MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	2039/22T, 2040/22T	020166	FRESENIUS MEDICAL CARE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

			DEUTSCHLAND GMBH	CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BALANCE 1.5% GLUCOSE, 1.25MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	2041/22T, 2042/22T	020162	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BALANCE 2.3% GLUCOSE, 1.25MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	2037/22T, 2038/22T	020164	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BALANCE 1.5% GLUCOSE,1.75MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	1917/22T, 1918/22T	020163	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BALANCE 2.3% GLUCOSE, 1.75MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	1913/22T, 1914/22T	020165	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BALANCE 4.25% GLUCOSE, 1.75MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	1915/22T, 1916/22T	020167	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MYCOPHENOLATE MOFETIL ACCORD CAPSULE, HARD 250MG	7822/22T	020915	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	8381/22T	020206	GRIFOLS DEUTSCHLAND GMBH.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
TAZOCIN EF POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/VIAL	6837/22T, 6838/22T, 6839/22T, 6840/22T	014384	PFIZER HELLAS AE	B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other variation B.I.z B.I.z - Quality change - Active substance - Other variation A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in

				the dossier)* B.I.c.2.z B.I.c.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the active substance - Other changes
VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	6556/22T	012082	PFIZER HELLAS AE	B.II.f.z B.II.f.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Other variation
CANESTEN CREAM 1%	7327/22T	004757	BAYER HELLAS ABEE	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
COSOPT IMULTI EYE DROPS, SOLUTION (20MG/5MG)/ML	4629/22T, 4630/22T, 4631/22T	022891	VIANEX S.A	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	8459/21T	020032	ALLERGAN PHARMACEUTICALS IRELAND	B.II.b.4.c B.II.b.4.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or the change in batch size requires a new bioequivalence study
BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	8458/21T	022400	ABBVIE PHARMACEUTICALS S.A.	B.II.b.4.c B.II.b.4.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The change

				requires assessment of the comparability of a biological/immunological medicinal product or the change in batch size requires a new bioequivalence study
VESICARE ORAL SUSPENSION 1MG/ML	4581/22T	022366	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VESICARE TABLET, FILM COATED 10MG	4579/22T	019751	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VESICARE TABLET, FILM COATED 10MG	4579/22T	019751	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VESICARE TABLET, FILM COATED 5MG	4580/22T	019727	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VESICARE TABLET, FILM COATED 5MG	4580/22T	019727	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VESICARE ORAL SUSPENSION 1MG/ML	4467/22T	022366	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VESICARE TABLET, FILM COATED 10MG	4468/22T	019751	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VESICARE TABLET, FILM COATED 5MG	4469/22T	019727	ASTELLAS PHARMACEU	A.1 A.1 - ADMINISTRATIVE

			TICALS A.E.B.E.	CHANGES - Change in the name and/or address of the marketing authorisation holder
BELKYRA SOLUTION FOR INJECTION 10MG/ML	4366/22T	022647	ABBVIE PHARMACEUTICALS S.A.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
NOSATEL TABLET, FILM COATED 25MG	4643/22T	020154	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
VESICARE ORAL SUSPENSION 1MG/ML	5793/22T, 5794/22T	022366	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-

				significant specification parameter (e.g. deletion of an obsolete parameter)
VESICARE TABLET, FILM COATED 10MG	5789/22T, 5790/22T	019751	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
VESICARE TABLET, FILM COATED 5MG	5791/22T, 5792/22T	019727	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	8186/22T	020564	CSL BEHRING GMBH	B.IV.1.a.1 B.IV.1.a.1 - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part

				of the primary packaging - Device with CE marking
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	8183/22T	023121	CSL BEHRING GMBH	B.IV.1.a.1 B.IV.1.a.1 - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking
BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	8185/22T	022321	CSL BEHRING GMBH	B.IV.1.a.1 B.IV.1.a.1 - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking
BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	8184/22T	023120	CSL BEHRING GMBH	B.IV.1.a.1 B.IV.1.a.1 - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	4543/22T	020032	ALLERGAN PHARMACEUTICALS IRELAND	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in

				QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
DUOKOPT EYE DROPS, SOLUTION 20MG/ML+5MG/ML	4975/22T, 4976/22T, 4977/22T	022317	LABORATOIRES THEA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MIFEGYNE TABLET 200MG	5115/22T	022983	EXELGYN	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits
SUTIREM CAPSULE, HARD 12.5MG	7381/22T	022953	REMEDICA LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SUTIREM CAPSULE, HARD 25MG	7380/22T	022954	REMEDICA LTD	B.I.z B.I.z - QUALITY

				CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SUTIREM CAPSULE, HARD 37.5MG	7379/22T	022955	REMEDICA LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SUTIREM CAPSULE, HARD 50MG	7378/22T	022956	REMEDICA LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
BILENI NASAL SPRAY, SUSPENSION	7935/22T	021884	MEDA PHARMACEUTICALS S.A.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
YASMIN TABLET, FILM COATED 0.03MG/3MG	7685/22T	022847	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
YASMINELLE TABLET, FILM COATED 0.02MG/3MG	7684/22T	020125	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
OCTORET SOLUTION FOR INJECTION OR INFUSION 40MG/ML	8914/21T, 8915/21T	023372	NORIDEM ENTERPRISES LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by th C.I.3.b C.I.3.b -

				SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by th C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implem
OCTORET SOLUTION FOR INJECTION OR INFUSION 80MG/ML	8916/21T, 8917/21T	023373	NORIDEM ENTERPRISES LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure

				concerning PSUR or PASS, or the outcome of the assessment done by th C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by th C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implem
OCTORET SOLUTION FOR INJECTION OR INFUSION 20MG/ML	8912/21T, 8913/21T	023371	NORIDEM ENTERPRISES LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by th C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by th C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implem
MONOPROST EYE DROPS, SOLUTION IN SINGLE DOSE CONTAINER 50MCG/ML	3828/22T, 3829/22T, 3830/22T, 3831/22T, 3832/22T	021947	LABORATOIRES THEA	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the

				batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finishe B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finishe B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and l
ERLOTINIB REMEDICA TABLET, FILM COATED 150MG	8936/22T	022495	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ERLOTINIB REMEDICA TABLET, FILM COATED 25MG	8938/22T	022492	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ERLOTINIB REMEDICA TABLET, FILM COATED 50MG	8939/22T	022493	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ERLOTINIB REMEDICA TABLET, FILM COATED 100MG	8937/22T	022494	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TUTECVI TABLET 50MG	4268/22T	023539	VIATRIS LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
FLUTIFORM PRESSURISED	3904/22T, 3905/22T	021396	MUNDIPHARMA	B.III.1.a.3 B.III.1.a.3 - QUALITY

INHALATION, SUSPENSION 125MCG/5MCG			PHARMACEUTICALS LTD	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 250MCG/10MCG	3906/22T, 3907/22T	021397	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 50MCG/5MCG	3908/22T, 3909/22T	021395	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active

				substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TAPTIQOM EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (15MCG/5MG)/ML	4156/22T, 4157/22T	022246	VIANEX S.A	B.II.a.3.b.1 B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients
TAPTIQOM EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (15MCG/5MG)/ML	9128/21T, 9129/21T	022246	VIANEX S.A	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the

				manufacturer/importer is responsible do not include batch release
EZETIMIBE ACCORD TABLET 10MG	4367/22T, 4368/22T, 4369/22T, 4370/22T, 4371/22T, 4372/22T	022812	ACCORD HEALTHCARE S.L.U	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f B.II.b.3.z B.II.b.3.z - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used
FUNGUSTATIN CAPSULE, HARD 150MG	3372/22T	013273	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	3373/22T	013275	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 125MCG/5MCG	6333/22T, 6334/22T, 6335/22T, 6336/22T	021396	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 50MCG/5MCG	6337/22T, 6338/22T, 6339/22T, 6340/22T	021395	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES -

				FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 250MCG/10MCG	6329/22T, 6330/22T, 6331/22T, 6332/22T	021397	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)
ALLUZIENCE SOLUTION FOR INJECTION 200 SPEYWOOD UNITS/ML	6519/22T	023486	IPSEN PHARMA	B.II.b.2.b B.II.b.2.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method
OLIMEL N9E EMULSION FOR INFUSION	5170/22T, 5171/22T, 5172/22T	022011	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL N7 EMULSION FOR INFUSION	5176/22T, 5177/22T, 5178/22T	022012	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL N12E EMULSION FOR INFUSION	5173/22T, 5174/22T, 5175/22T	023257	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL N7E EMULSION FOR INFUSION	5167/22T, 5168/22T, 5169/22T	022010	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL N9 EMULSION FOR INFUSION	5179/22T, 5180/22T, 5181/22T	022013	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
OLIMEL PERI N4E EMULSION FOR INFUSION	5164/22T, 5165/22T, 5166/22T	022008	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
WELLBUTRIN XR MODIFIED-RELEASE TABLET 150MG	3561/22T	020248	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
WELLBUTRIN XR MODIFIED-RELEASE TABLET 300MG	3562/22T	020249	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of

				the currently approved pack sizes
NETILMICIN/DEXAMETHASONE NEWLINE PHARMA EYE DROPS, SOLUTION (3MG/1MG)/ML	9776/21T	023326	NEWLINE PHARMA, S.L.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NETILMICIN/DEXAMETHASONE NEWLINE PHARMA EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (3MG/1MG)/ML	9775/21T	023327	NEWLINE PHARMA, S.L.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NETILMICIN/DEXAMETHASONE NEWLINE PHARMA	7494/21T	023326	NEWLINE PHARMA, S.L.	C.I.8.a C.I.8.a - SAFETY, EFFICACY,

EYE DROPS, SOLUTION (3MG/1MG)/ML				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
NETILMICIN/DEXAMETHASONE NEWLINE PHARMA EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (3MG/1MG)/ML	7493/21T	023327	NEWLINE PHARMA, S.L.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
MEDOCRIPTINE TABLET 2.5MG	9202/22T	010640	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosi

				milar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BROT TABLET, FILM COATED 500MG	9139/22T	009817	MEDOCHE MIE LTD	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms
SIRANALEN CAPSULE, HARD 75MG	4323/22T	022530	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SIRANALEN CAPSULE, HARD 150MG	4322/22T	022531	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SIRANALEN CAPSULE, HARD 300MG	4321/22T	022532	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NAROX TABLET, FILM COATED 30MG	8922/22T, 8923/22T	022265	DELORBIS PHARMACEUTICALS LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing

				process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
NAROX TABLET, FILM COATED 60MG	8920/22T, 8921/22T	022266	DELORBIS PHARMACEUTICALS LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
NAROX TABLET, FILM COATED 90MG	8918/22T, 8919/22T	022267	DELORBIS PHARMACEUTICALS LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except

				batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
NAROX TABLET, FILM COATED 120MG	8916/22T, 8917/22T	022268	DELORBIS PHARMACEUTICALS LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
AROTAN TABLET, FILM COATED 20MG	9008/22T	021020	DELORBIS PHARMACEUTICALS LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
AROTAN TABLET, FILM COATED 10MG	9009/22T	021019	DELORBIS PHARMACEUTICALS LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
VALCYTE TABLET, FILM COATED 450MG	6752/22T	020089	ROCHE (HELLAS) SA	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
VALCYTE POWDER FOR ORAL SOLUTION 50MG/ML	6751/22T	020549	ROCHE (HELLAS) SA	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
VALCYTE TABLET, FILM COATED 450MG	5218/22T, 5219/22T, 5220/22T, 5221/22T, 5222/22T	020089	ROCHE (HELLAS) SA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the

				Pharmacovigilance System Master File (PSMF) location B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
VALCYTE POWDER FOR ORAL SOLUTION 50MG/ML	5213/22T, 5214/22T, 5215/22T, 5216/22T, 5217/22T	020549	ROCHE (HELLAS) SA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location B.II.b.1.a B.II.b.1.a - QUALITY

				CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
VERRIA TABLET, FILM COATED 50MG	3902/22T	022536	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VERRIA TABLET, FILM COATED 200MG	3903/22T	022537	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
INTRATECT SOLUTION FOR INFUSION 50G/L	4126/22T, 4127/22T	021466	BIOTEST PHARMA GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of

				an analytical procedure for an in-process control
INTRATECT SOLUTION FOR INFUSION 100G/L	4128/22T, 4129/22T	022263	BIOTEST PHARMA GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
DEXAMETHASONE/KABI SOLUTION FOR INJECTION 4MG/ML	3256/22T	023654	FRESENIUS KABI HELLAS A.E.	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	6458/22T	023238	ACCORD HEALTHCARE S.L.U	B.I.z B.I.z - Quality change - Active substance - Other variation
URSOFALK ORAL SUSPENSION 250MG/5ML	9098/22T	020790	DR. FALK PHARMA GMBH	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control

				testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
URSOFALK ORAL SUSPENSION 250MG/5ML	4895/22T, 4896/22T, 4897/22T	020790	DR. FALK PHARMA GMBH	B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes
SPECENIB TABLET, FILM COATED 50MG	8502/22T	023046	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a

				marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
SPECENIB TABLET, FILM COATED 100MG	8499/22T	023049	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
SPECENIB TABLET, FILM COATED 140MG	8498/22T	023050	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
SPECENIB TABLET, FILM COATED 80MG	8500/22T	023048	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP

				changes (e.g. agreed wording + template change)
SPECENIB TABLET, FILM COATED 70MG	8501/22T	023047	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
SPECENIB TABLET, FILM COATED 20MG	8503/22T	023045	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
VOLULYTE SOLUTION FOR INFUSION 6%	6854/22T, 6855/22T	20656	FRESENIUS KABI DEUTSCHLAND GMBH, GERMANY	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by

				the MAH where significant assessment by the competent authority is required*
DASATINIB PHARMASCIENCE TABLET, FILM COATED 20MG	4549/22T	023312	PHARMASCIENCE INTERNATIONAL LTD	C.I.13 C.I.13 - C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - Submission of additional clinical and non-clinical studies, including BE-studies.
DASATINIB PHARMASCIENCE TABLET, FILM COATED 50MG	4548/22T	023313	PHARMASCIENCE INTERNATIONAL LTD	C.I.13 C.I.13 - C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - Submission of additional clinical and non-clinical studies, including BE-studies.
DASATINIB PHARMASCIENCE TABLET, FILM COATED 80MG	4546/22T	023315	PHARMASCIENCE INTERNATIONAL LTD	C.I.13 C.I.13 - C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - Submission of additional clinical and non-clinical studies, including BE-studies.
DASATINIB PHARMASCIENCE TABLET, FILM COATED 140MG	4544/22T	023317	PHARMASCIENCE INTERNATIONAL LTD	C.I.13 C.I.13 - C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - Submission of additional clinical and non-clinical studies, including BE-studies.
DASATINIB PHARMASCIENCE TABLET, FILM COATED 70MG	4547/22T	023314	PHARMASCIENCE INTERNATIONAL LTD	C.I.13 C.I.13 - C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - Submission of additional clinical and non-clinical studies, including BE-studies.
DASATINIB PHARMASCIENCE TABLET, FILM COATED 100MG	4545/22T	023316	PHARMASCIENCE INTERNATIONAL LTD	C.I.13 C.I.13 - C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - Submission of additional clinical and non-clinical studies, including BE-studies.
SPECENIB TABLET, FILM COATED 50MG	9093/22T	023046	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
SPECENIB TABLET, FILM COATED 100MG	9090/22T	023049	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
SPECENIB TABLET, FILM COATED 140MG	9089/22T	023050	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
SPECENIB TABLET, FILM COATED 20MG	9094/22T	023045	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
SPECENIB TABLET, FILM COATED 80MG	9091/22T	023048	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
SPECENIB TABLET, FILM COATED 70MG	9092/22T	023047	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
GAVISCON PEPPERMINT TABLET, CHEWABLE	5682/22T	021162	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GAVISCON STRAWBERRY FLAVOUR TABLET, CHEWABLE	5681/22T	022395	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GAVISCON LIQUID SACHETS	5680/22T	021163	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AGREGEX TABLET, FILM COATED 75MG	8108/22T	20666	TEVA BV	A.7 A.7 - ADMINISTRATIVE CHANGES -

				Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
OLANZAPINE ACCORD TABLET, FILM COATED 5MG	8303/22T	021413	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
OLANZAPINE ACCORD TABLET, FILM COATED 10MG	8302/22T	021415	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML IN PRE-FILLED SYRINGE	3920/22T	021908	FRESENIUS KABI HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer

				responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML	3923/22T	020063	FRESENIUS KABI HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML	3922/22T	020064	FRESENIUS KABI HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML IN PRE-FILLED SYRINGE	3921/22T	021907	FRESENIUS KABI HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient

				(when mentioned in the dossier)*
CERTICAN TABLET 0.5MG	4244/22T	019643	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
CERTICAN TABLET 0.75MG	4245/22T	019644	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
CERTICAN TABLET 0.25MG	4247/22T	019642	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or

				Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
CERTICAN TABLET 1MG	4246/22T	019645	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
STRIVERDI RESPIMAT SOLUTION FOR INHALATION	4338/22T	022003	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SOLPADEINE HEADACHE EFFERVESCENT TABLET 500MG/65MG	7620/22T	022563	OMEGA PHARMA HELLAS S.A	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State -

				Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
TESTOGEL GEL 50MG	6118/22T	020520	LABORATOIRES BESINS INTERNATIONAL	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
TESTOGEL GEL 25MG	6119/22T	020590	LABORATOIRES BESINS INTERNATIONAL	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
ALMIRAL GEL 1% W/W	9006/22T	012468	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which

				no new additional data is required to be submitted by the MAH
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 5MG/1.5ML	1418/22T	020802	NOVO NORDISK A/S	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	1421/22T	020990	NOVO NORDISK A/S	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	1422/22T	020991	NOVO NORDISK A/S	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing

				process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	1423/22T	020992	NOVO NORDISK A/S	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 10MG/1.5ML	1419/22T	020803	NOVO NORDISK A/S	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	1424/22T	022993	NOVO NORDISK A/S	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance -

				Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	1426/22T	022995	NOVO NORDISK A/S	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	1425/22T	022994	NOVO NORDISK A/S	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate

NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 15MG/1.5ML	1420/22T	020804	NOVO NORDISK A/S	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
MEDOFLUCON CAPSULE, HARD 200MG	8941/22T	019830	MEDOCHEMIE LTD	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
MEDOFLUCON CAPSULE, HARD 50MG	8942/22T	012700	MEDOCHEMIE LTD	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
MEDOFLUCON CAPSULE, HARD 150MG	8940/22T	012701	MEDOCHEMIE LTD	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished

				product - Change outside the approved specifications limits range
LEVOFLOXACIN NORIDEM SOLUTION FOR INFUSION 5MG/ML	3779/22T	021277	NORIDEM ENTERPRISES LTD	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
LEVOFLOXACIN NORIDEM SOLUTION FOR INFUSION 5MG/ML	6354/22T, 6355/22T	021277	NORIDEM ENTERPRISES LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
FUCICORT CREAM	8647/22T	008675	LEO PHARMA A/S	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MAALOX PLUS ORAL SUSPENSION	8830/22T, 8831/22T	019265	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
RAPIBLOC POWDER FOR SOLUTION FOR INFUSION 300MG/VIAL	4285/22T	022744	AMOMED PHARMA GMBH.	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
BENDAMUSTINE ACCORD POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 2.5MG/ML	2427/21T	022411	ACCORD HEALTHCARE S.L.U	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
FLUOROURACIL ACCORD SOLUTION FOR INJECTION OR INFUSION 50MG/ML	5586/21T	021926	ACCORD HEALTHCARE S.L.U	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	8360/22T	020570	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	8359/22T	020571	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	8358/22T	020572	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and

				quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	8357/22T	020573	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	8953/21T	020252	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8955/21T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	8963/21T	016177	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	8964/21T	016178	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VALTREX TABLET, FILM COATED 500MG	8958/21T	016180	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROXAT TABLET, FILM COATED 20MG	8959/21T	014178	GLAXOSMITHKLINE	A.1 A.1 - ADMINISTRATIVE

			(IRELAND) LIMITED	CHANGES - Change in the name and/or address of the marketing authorisation holder
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	8952/21T	018647	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 2MG	8965/21T	022006	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/100MCG	8960/21T	022630	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/250MCG	8961/21T	022631	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	8967/21T	016176	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DUODART CAPSULE, HARD	8970/21T	020719	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	8968/21T	018617	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZINACEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 750MG	8956/21T	019521	SANDOZ PHARMACEUTICALS D.D.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
ZINACEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 1.5G	8957/21T	019520	SANDOZ PHARMACEUTICALS D.D.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	8951/21T	017527	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	8966/21T	018618	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	8954/21T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/500MCG	8962/21T	022632	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BACTROBAN CREAM 2%(W/W)	8969/21T	022917	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TRIATEC TABLET 2.5MG	5487/22T	012904	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TRIATEC TABLET 5MG	5486/22T	012905	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

TRIATEC TABLET 2.5MG	6002/22T	012904	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TRIATEC TABLET 5MG	6001/22T	012905	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPOCAT TABLET, FILM COATED 10MG/80MG	7266/22T	023452	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LIPOCAT TABLET, FILM COATED 10MG/20MG	7268/22T	023450	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LIPOCAT TABLET, FILM COATED 10MG/40MG	7267/22T	023451	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture

				of the finished product - Minor change in the manufacturing process
LIPOCAT TABLET, FILM COATED 10MG/10MG	7269/22T	023449	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LIPOCAT TABLET, FILM COATED 10MG/10MG	6999/22T, 7000/22T	023449	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LIPOCAT TABLET, FILM COATED 10MG/80MG	6993/22T, 6994/22T	023452	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LIPOCAT TABLET, FILM COATED 10MG/20MG	6997/22T, 6998/22T	023450	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active

				substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LIPOCAT TABLET, FILM COATED 10MG/40MG	6995/22T, 6996/22T	023451	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LIPOCAT TABLET, FILM COATED 10MG/10MG	9189/21T	023449	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
LIPOCAT TABLET, FILM COATED 10MG/80MG	9192/21T	023452	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
LIPOCAT TABLET, FILM COATED 10MG/20MG	9190/21T	023450	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product

				- Minor changes to an approved test procedure
LIPOCAT TABLET, FILM COATED 10MG/40MG	9191/21T	023451	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
BRUFEDOL TABLET, PROLONGED-RELEASE 800MG	640/22T	023728	VIATRIS HEALTHCARE LIMITED.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SEDISTRESS TABLET, COATED 200MG	7220/21T	021217	TILMAN S.A.	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
SYNTOFLOX TABLET, FILM COATED 250MG	8639/22T	020588	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SYNTOFLOX TABLET, FILM COATED 500MG	8638/22T	20589	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 5/160/25MG	5734/22T	023476	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/160/12.5MG	5733/22T	023477	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/160/25MG	5736/22T	023478	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended

				to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/320/25MG	5732/22T	023479	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 5/160/12.5MG	5735/22T	023475	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 5/160/25MG	7538/22T	023476	MYLAN IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/160/12.5MG	7537/22T	023477	MYLAN IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/320/25MG	7535/22T	023479	MYLAN IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and

				conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 5/160/12.5MG	7539/22T	023475	MYLAN IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/160/25MG	7536/22T	023478	MYLAN IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
BENDAMUSTINE ACCORD POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 2.5MG/ML	2428/21T, 2429/21T, 2430/21T	022411	ACCORD HEALTHCARE S.L.U	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture

				of the active substance (where specified in the technical doss B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele
MAALOX ORAL SUSPENSION (22.8+40)MG/ML	8734/22T, 8735/22T	019266	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 -

				ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MAALOX PLUS ORAL SUSPENSION	8793/22T, 8794/22T	019265	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
VIMETSO TABLET, FILM COATED 50MG/1000MG	4170/22T	023481	TAD PHARMA GMBH	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the

				restricted part of an Active Substance Master File
VIMETSO TABLET, FILM COATED 50MG/850MG	4169/22T	023480	TAD PHARMA GMBH	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
VIMETSO TABLET, FILM COATED 50MG/1000MG	3030/22T	023481	TAD PHARMA GMBH	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
VIMETSO TABLET, FILM COATED 50MG/850MG	3029/22T	023480	TAD PHARMA GMBH	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
EUCARBON TABLET	8508/22T, 8509/22T, 8510/22T	016776	F. TRENKA CHEM.-PHARMAZEUTISCHE FABRIK GES. M.B.H.	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for

				the finished product - Minor changes to an approved test procedure B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
VIMETSO TABLET, FILM COATED 50MG/1000MG	5853/22T	023481	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
VIMETSO TABLET, FILM COATED 50MG/850MG	5854/22T	023480	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
HYDROXYCHLOROQUINE SULFATE ACCORD TABLET, FILM COATED 200MG	3974/22T	023189	ACCORD HEALTHCARE S.L.U	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate
ROCURONIUM B.BRAUN SOLUTION FOR INJECTION OR INFUSION 10MG/ML	7225/21T	023414	B. BRAUN MELSUNGEN AG	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
ROCURONIUM B.BRAUN SOLUTION FOR INJECTION OR INFUSION 10MG/ML	7229/22T	023414	B. BRAUN MELSUNGEN AG	B.II.c.1.b B.II.c.1.b - QUALITY CHANGES - FINISHED

				PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method
DAMIRAST TABLET, FILM COATED 500MCG	6195/22T	023360	ELPEN PHARMACEUTICAL CO INC	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
EXTRANEAL SOLUTION FOR PERITONEAL DIALYSIS	4973/21T	023288	BAXTER (HELLAS) EPE	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
EXTRANEAL SOLUTION FOR PERITONEAL DIALYSIS	9205/21T	023288	BAXTER (HELLAS) EPE	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage

				conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
LOSARTAN AUROBINDO TABLET, FILM COATED 50MG	3924/22T, 3925/22T, 3926/22T	023012	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.4 B.III.1.a.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

				Deletion of certificates (in case multiple certificates exist per material)
DOTAREM SOLUTION FOR INJECTION 0.5MMOL/ML (VIALS MULTIPLE USE)	3033/22T, 3034/22T	022074	GUERBET	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
DOTAREM SOLUTION FOR INJECTION 0.5MMOL/ML (VIALS SINGLE USE)	3031/22T, 3032/22T	022073	GUERBET	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
DOTAREM SOLUTION FOR INJECTION IN PREFILLED SYRINGES 0.5MMOL/ML	3035/22T, 3036/22T	022075	GUERBET	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing

				process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 20MG	3579/22T	022170	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 40MG	3580/22T	022171	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur.

				Monograph - Updated certificate from an already approved manufacturer
VISIPAQUE INJECTION 270MGI/ML	6802/21T	019102	GE HEALTHCARE AS (NYDALEN)	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
VISIPAQUE INJECTION 320MGI/ML	6803/21T	019098	GE HEALTHCARE AS (NYDALEN)	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
VISIPAQUE INJECTION 270MGI/ML	3927/21T, 3928/21T	019102	GE HEALTHCARE AS (NYDALEN)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VISIPAQUE INJECTION 320MGI/ML	3929/21T, 3930/21T	019098	GE HEALTHCARE AS (NYDALEN)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	2348/22T	019523	SANOFI PASTEUR.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
GRAFALON CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	4748/22T	017186	NEOVII BIOTECH GMBH	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure

				system - Other variation
OMNIPAQUE SOLUTION FOR INJECTION 300MGI/ML	5980/21T, 5981/21T, 5982/21T, 5983/21T, 5984/21T, 5985/21T, 5986/21T, 5987/21T, 5988/21T, 5989/21T, 5990/21T	017965	GE HEALTHCARE AS (NYDALEN)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OMNIPAQUE SOLUTION FOR INJECTION 350MGI/ML	5991/21T, 5992/21T, 5993/21T, 5994/21T, 5995/21T, 5996/21T, 5997/21T, 5998/21T, 5999/21T, 6000/21T, 6001/21T	017967	GE HEALTHCARE AS (NYDALEN)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GRAFALON CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	9284/21T	017186	NEOVII BIOTECH GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
EPLERENONE ACCORD TABLET, FILM COATED 25MG	7710/22T	022368	ACCORD HEALTHCARE S.L.U	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
EPLERENONE ACCORD TABLET, FILM COATED 50MG	7709/22T	022369	ACCORD HEALTHCARE S.L.U	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
STRIVERDI RESPIMAT SOLUTION FOR INHALATION	8312/22T	022003	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits
ULTRAVIST 370 SOLUTION FOR INJECTION 76.9%	4588/22T, 4589/22T, 4590/22T, 4591/22T	018966	BAYER HELLAS ABEE	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer

				responsible for importation B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its correspo
DALMEVIN TABLET 50MG	6258/22T, 6259/22T	022644	MEDOCHE MIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ALMIRAL TABLET, GASTRO-RESISTANT 25MG	7854/22T	009918	MEDOCHE MIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation

ALMIRAL TABLET, GASTRO-RESISTANT 50MG	7855/22T	009919	MEDOCHE MIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
PULMICORT TURBUHALER POWDER FOR INHALATION 100MCG/DOSE	8828/22T	013186	ASTRAZENECA AB	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
PULMICORT TURBUHALER POWDER FOR INHALATION 200MCG/DOSE	8829/22T	013187	ASTRAZENECA AB	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
BEROZOL POWDER FOR SOLUTION FOR INJECTION 40MG/VIAL	7750/22T, 7751/22T, 7752/22T	021720	SAPIENS PHARMACEUTICALS LTD	B.II.g.5.b B.II.g.5.b - QUALITY CHANGES - FINISHED PRODUCT - Design Space and post approval change management protocol - Implementation of changes foreseen in an approved change management protocol - The implementation of the change requires further supportive data
GYRABLOCK TABLET, FILM COATED 400MG	4764/22T	011772	MEDOCHEMIE LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
DAMIRAST TABLET, FILM COATED 500MCG	7653/21T	023360	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
RAMIMED HCT TABLET 5MG/25MG	849/22T	020426	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
RAMIMED HCT TABLET 2.5MG/12.5MG	848/22T	020425	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FOSTER NEXTHALER POWDER FOR INHALATION (200MCG/6MCG)/DOSE	3952/22T	023232	CHIESI FARMACEUTICI SPA	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ONDANSETRON ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	4269/22T	020718	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
THALIDOMIDE ACCORD CAPSULE, HARD 50MG	4238/22T	023094	ACCORD HEALTHCARE S.L.U	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	4173/22T, 4174/22T	022345	BIOTEST PHARMA GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other

				regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
TACROLIMUS ACCORD OINTMENT 0.1%	3741/22T, 3742/22T, 3743/22T	023599	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.3.a B.II.b.3.a - QUALITY

				CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	6008/22T	022345	BIOTEST PHARMA GMBH	B.II.d.2.e B.II.d.2.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur.
PRELYNCA CAPSULE, HARD 100MG	8234/22T	022468	PHARMATHEN S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRELYNCA CAPSULE, HARD 25MG	8237/22T	022465	PHARMATHEN S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRELYNCA CAPSULE, HARD 150MG	8233/22T	022469	PHARMATHEN S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRELYNCA CAPSULE, HARD 225MG	8231/22T	022471	PHARMATHEN S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRELYNCA CAPSULE, HARD 50MG	8236/22T	022466	PHARMATHEN S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the

				name and/or address of the marketing authorisation holder
PRELYNCA CAPSULE, HARD 300MG	8230/22T	022472	PHARMATHEN S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRELYNCA CAPSULE, HARD 75MG	8235/22T	022467	PHARMATHEN S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRELYNCA CAPSULE, HARD 200MG	8232/22T	022470	PHARMATHEN S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SALOFALK TABLET, GASTRO-RESISTANT 1G	7760/22T	023177	DR. FALK PHARMA GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
SALOFALK ENEMA 4G/60ML	7759/22T	012246	DR. FALK PHARMA GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the

				active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
SALOFALK TABLET, GASTRO-RESISTANT 500MG	7758/22T	013056	DR. FALK PHARMA GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
SALOFALK SUPPOSITORY 500MG	7757/22T	013057	DR. FALK PHARMA GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
TICAGRELOR/MYLAN TABLET, FILM COATED 90MG	7823/22T, 7824/22T	023358	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

				A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
METOCLOPRAMIDE ACCORD TABLET 10MG	5014/22T	021237	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
METOCLOPRAMIDE ACCORD TABLET 10MG	7487/22T, 7488/22T	021237	ACCORD HEALTHCARE S.L.U	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site

				where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	5240/22T	019523	SANOFI PASTEUR.	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
AGGRASTAT CONCENTRATE FOR SOLUTION FOR INFUSION 0.25MG/ML	6948/22T, 6949/22T	018260	CORREVIO	B.I.a.1.d B.I.a.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - New manufacturer of material for which an assessment is required of viral safety and/or TSE risk B.I.a.4.d B.I.a.4.d -

				QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the active substance
OLANZAPINE ACCORD TABLET, FILM COATED 5MG	7363/22T, 7364/22T, 7365/22T, 7366/22T, 7367/22T, 7368/22T, 7369/22T, 7370/22T, 7371/22T, 7372/22T	021413	ACCORD HEALTHCARE S.L.U	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finis B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture
OLANZAPINE ACCORD TABLET, FILM COATED 10MG	7353/22T, 7354/22T, 7355/22T, 7356/22T, 7357/22T, 7358/22T, 7359/22T, 7360/22T, 7361/22T, 7362/22T	021415	ACCORD HEALTHCARE S.L.U	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finis B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site

				for part or all of B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	6812/21T	022396	SANOFI PASTEUR.	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
POTASSIUM IODIDE G.L.PHARMA TABLET 65MG	7149/21T	021773	G.L. PHARMA GMBH	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the

				finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
AMODUO TABLET 10MG/10MG	8319/22T	022656	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
AMODUO TABLET 5MG/5MG	8322/22T	022653	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
AMODUO TABLET 10MG/5MG	8320/22T	022655	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure

AMODUO TABLET 5MG/10MG	8321/22T	022654	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
DELAZO EYE DROPS, SOLUTION 20MG/ML	9619/21T, 9620/21T	023180	PHARMATHEN S.A.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
STORILAT R TABLET, PROLONGED-RELEASE 400MG	8403/22T	014793	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

FLUTICAPEN INHALATION POWDER, PRE-DISPENSED 250MCG/DOSE	4761/22T, 4762/22T, 4763/22T	020599	ELPEN PHARMACEUTICAL CO INC	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
FLUTICAPEN INHALATION POWDER, PRE-DISPENSED 500MCG/DOSE	4758/22T, 4759/22T, 4760/22T	020600	ELPEN PHARMACEUTICAL CO INC	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.I.b.2.a B.I.b.2.a - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
AMARYL TABLET 2MG	6000/22T	20551	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 4MG	5999/22T	20553	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	6730/22T, 6731/22T, 6732/22T	019724	MERCK SHARP & DOHME BV	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of

				the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
VALTREX TABLET, FILM COATED 500MG	5788/22T	016180	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
CLIFT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	4552/22T	022666	VIATRIS LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which

				no new additional data is required to be submitted by the MAH
DYSPORT POWDER FOR SOLUTION FOR INJECTION 500U	8669/22T, 8670/22T, 8671/22T, 8672/22T	019337	IPSEN M.E.P.E.	B.I.a.4.a B.I.a.4.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Tightening of in-process limits B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits
TELFAST TABLET, FILM COATED 180MG	8833/22T	018151	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms
LEVOXA TABLET, FILM COATED 500MG	5807/22T, 5808/22T	021993	TEVA BV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MST CONTINUS TABLET, PROLONGED-RELEASE 100MG	8588/22T	019748	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits
MST CONTINUS TABLET, PROLONGED-RELEASE 10MG	8585/22T	019746	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits
MST CONTINUS TABLET, PROLONGED-RELEASE 60MG	8586/22T	019747	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits

MST CONTINUS TABLET, PROLONGED-RELEASE 30MG	8587/22T	019745	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits
AZIPRON TABLET 1MG	8313/22T, 8314/22T	022280	REMEDICA LTD	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
FUSIDIC ACID/BETAMETHASONE VALERATE PHARMASCIENCE INTERNATIONAL CREAM (20MG/1MG)/G	8143/22T	022726	PHARMASCIENCE INTERNATIONAL LTD	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
BILAZ ORAL SOLUTION 2.5MG/ML	3763/22T, 3764/22T	022853	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product,

				including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits
AMARYL TABLET 2MG	4194/22T	20551	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMARYL TABLET 3MG	4193/22T	20552	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMARYL TABLET 4MG	4192/22T	20553	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMARYL TABLET 1MG	4195/22T	020550	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FIXAPROST EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (50MCG/5MG)/ML	4159/22T	023359	LABORATOIRES THEA	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	3686/22T	019724	MERCK SHARP & DOHME BV	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
NOSATEL TABLET, FILM COATED 25MG	4872/22T, 4873/22T, 4874/22T	020154	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product

				- Other changes B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product
EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	6796/22T, 6797/22T, 6798/22T	023238	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product -

				Primary packaging site
EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	3975/22T	023238	ACCORD HEALTHCARE S.L.U	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	5143/22T	019724	MERCK SHARP & DOHME BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RUVOMINOX GEL 1%	8144/22T	013783	COSTAKIS TSISIOS & CO. LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MUCOBROXOL SYRUP 15MG/5ML	8584/22T	019999	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
FAMOPSIN TABLET, FILM COATED 20MG	8532/22T, 8533/22T	011971	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FAMOPSIN TABLET, FILM COATED 40MG	8530/22T, 8531/22T	011972	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active

				substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SYNTOSARTIN TABLET 150MG	8728/22T, 8729/22T, 8730/22T, 8731/22T	020976	CODAL-SYNTO LIMITED	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex
SYNTOSARTIN TABLET 300MG	8724/22T, 8725/22T, 8726/22T, 8727/22T	020977	CODAL-SYNTO LIMITED	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site

				for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex
TOBI SOLUTION FOR INHALATION 300MG/5ML	8506/22T, 8507/22T	019439	MYLAN IRE HEALTHCARE LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.z B.I.z - Quality change - Active substance - Other variation
ARIPIPRAZOLE AUROBINDO TABLET 10MG	4618/22T	022292	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ARIPIPRAZOLE AUROBINDO TABLET 30MG	4616/22T	022294	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ARIPIPRAZOLE AUROBINDO TABLET 15MG	4617/22T	022293	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DENAZOX TABLET 60MG	8353/22T, 8354/22T, 8355/22T	011974	REMEDICA LTD	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.c B.II.d.1.c - QUALITY CHANGES -

				FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	1938/22T, 1939/22T, 1940/22T	023151	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	1935/22T, 1936/22T, 1937/22T	023150	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material,

				reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	1932/22T, 1933/22T, 1934/22T	023149	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	1929/22T, 1930/22T, 1931/22T	023148	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer

				responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
DUODOPA INTESTINAL GEL	3435/22T, 3436/22T	019725	ABBVIE PHARMACEUTICALS S.A.	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIVERAM TABLET, FILM COATED 20MG/5MG/5MG	8742/21T, 8743/21T	022773	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIVERAM TABLET, FILM COATED 20MG/10MG/5MG	8744/21T, 8745/21T	022774	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
TRIVERAM TABLET, FILM COATED 40MG/10MG/10MG	8748/21T, 8749/21T	022776	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIVERAM TABLET, FILM COATED 20MG/10MG/10MG	8746/21T, 8747/21T	022775	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIVERAM TABLET, FILM COATED 10MG/5MG/5MG	8740/21T, 8741/21T	022772	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VITIS VINIFERA/OPELLA TABLET, FILM COATED 360MG	287/22T	023393	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	3300/22T	023151	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) -

				Replacement or addition of a supplier
TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	3299/22T	023150	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	3298/22T	023149	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	3297/22T	023148	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 5MG/1.5ML	8432/21T, 8433/21T, 8434/21T, 8435/21T, 3409/22T, 3410/22T, 3411/22T	020802	NOVO NORDISK A/S	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance

				B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.I.a.4.d B.I.a.4.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have a significant effec
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	8444/21T, 8445/21T, 8446/21T, 8447/21T, 3418/22T, 3419/22T, 3420/22T	020990	NOVO NORDISK A/S	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.I.a.4.d B.I.a.4.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have a significant effec
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	8448/21T, 8449/21T, 8450/21T, 8451/21T, 3421/22T, 3422/22T, 3423/22T	020991	NOVO NORDISK A/S	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture -

				Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.I.a.4.d B.I.a.4.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have a significant effec
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	8452/21T, 8453/21T, 8454/21T, 8455/21T, 3424/22T, 3425/22T, 3426/22T	020992	NOVO NORDISK A/S	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the

				active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.I.a.4.d B.I.a.4.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have a significant effec
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 10MG/1.5ML	8436/21T, 8437/21T, 8438/21T, 8439/21T, 3412/22T, 3413/22T, 3414/22T	020803	NOVO NORDISK A/S	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological /

				immunological substance or use of a different chemically derived substance in B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.I.a.4.d B.I.a.4.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have a significant effec
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	8420/21T, 8421/21T, 8422/21T, 8423/21T, 3400/22T, 3401/22T, 3402/22T	022993	NOVO NORDISK A/S	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different

				chemically derived substance in B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.I.a.4.d B.I.a.4.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have a significant effec
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	8428/21T, 8429/21T, 8430/21T, 8431/21T, 3406/22T, 3407/22T, 3408/22T	022995	NOVO NORDISK A/S	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in B.I.a.3.e B.I.a.3.e -

				QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.I.a.4.d B.I.a.4.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have a significant effec
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	8424/21T, 8425/21T, 8426/21T, 8427/21T, 3403/22T, 3404/22T, 3405/22T	022994	NOVO NORDISK A/S	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.I.a.4.d B.I.a.4.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have a significant effec
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 15MG/1.5ML	8440/21T, 8441/21T, 8442/21T, 8443/21T, 3415/22T, 3416/22T, 3417/22T	020804	NOVO NORDISK A/S	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch

				size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.I.a.4.d B.I.a.4.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have a significant effec
CONTROLOC TABLET, GASTRO-RESISTANT 40MG	4319/22T	018192	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONTROLOC TABLET, GASTRO-RESISTANT 20MG	4320/22T	018607	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DUODOPA INTESTINAL GEL	6179/22T	019725	ABBVIE PHARMACEUTICALS S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PHYSIONEAL 40 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	2783/22T, 2784/22T	022312	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release

				arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PHYSIONEAL 40 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86%	2787/22T, 2788/22T	022314	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PHYSIONEAL 35 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	2791/22T, 2792/22T	022310	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PHYSIONEAL 40 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	2785/22T, 2786/22T	022313	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

				B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PHYSIONEAL 35 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	2793/22T, 2794/22T	022309	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PHYSIONEAL 35 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-	2789/22T, 2790/22T	022311	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY

FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86% W/V				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PARACETAMOL ACCORD TABLET 500MG	5559/22T	022579	ACCORD HEALTHCARE S.L.U	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product
VESICARE ORAL SUSPENSION 1MG/ML	6559/22T	022366	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or

				storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
NIZORAL SHAMPOO 20MG/G	6231/22T	012220	STADA ARZNEIMITTEL AG	B.II.a.3.a.1 B.II.a.3.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Addition , deletion or replacement
VOLTAREN SUPPOSITORY 50MG	8574/22T	018443	NOVARTIS IRELAND LIMITED	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
VOLTAREN FOR CHILDREN SUPPOSITORY 12.5MG	8575/22T	018454	NOVARTIS IRELAND LIMITED	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the

				active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
VOLTAREN SUPPOSITORY 100MG	8573/22T	018400	NOVARTIS IRELAND LIMITED	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
DORZOTIM EYE DROPS, SOLUTION	8073/22T	021075	SAPIENS PHARMACEUTICALS LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
COVERSYL TABLET, FILM COATED 10MG	3634/22T	020031	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COVERAM TABLET 5MG/5MG	3628/22T	020465	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COVERAM TABLET 5MG/10MG	3629/22T	020466	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the

				relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COVERAM TABLET 10MG/5MG	3630/22T	020467	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VIACORAM TABLET 3.5MG/2.5MG	3622/22T	022642	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/10MG	3619/22T	022157	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/5MG	3620/22T	022158	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VIACORAM TABLET 7MG/5MG	3623/22T	022643	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COSYREL TABLET, FILM COATED 5MG/10MG	3625/22T	022634	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COSYREL TABLET, FILM COATED 10MG/5MG	3626/22T	022635	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COSYREL TABLET, FILM COATED 10MG/10MG	3627/22T	022636	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COSYREL TABLET, FILM COATED 5MG/5MG	3624/22T	022633	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/5MG	3618/22T	022156	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COVERAM TABLET 10MG/10MG	3631/22T	020468	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/10MG	3621/22T	022159	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COVERSYL TABLET, FILM COATED 2.5MG	3632/22T	020029	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
COVERSYL TABLET, FILM COATED 5MG	3633/22T	020030	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMINOPLASMAL B. BRAUN 10% E SOLUTION FOR INFUSION 100G/L	4341/22T, 4342/22T, 4343/22T, 4344/22T	022836	B. BRAUN MELSUNGEN AG	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia A.7 A.7 - ADMINISTRATIVE

				CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting B.III.1.a.4 B.III.1.a.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia
DUOMAX TABLET, FILM COATED 500MG/150MG	8046/22T	023101	MEDOCHEMIE LTD	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
GADOGRAF SOLUTION FOR INJECTION 1.0MMOL/ML	8756/21T	023258	BAYER HELLAS ABEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data

GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	8757/21T	022534	BAYER HELLAS ABEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GADOVIST PFS SOLUTION FOR INJECTION IN PREFILLED SYRINGES 1MMOL/ML	8758/21T	022535	BAYER HELLAS ABEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
DEMOLOX POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG/VIAL	1954/22T	022414	NORIDEM ENTERPRISES LTD	B.II.b.4.d B.II.b.4.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes
DEMOLOX POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG/VIAL	2509/22T	022414	NORIDEM ENTERPRISES LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a

				starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
EPLERENONE ACCORD TABLET, FILM COATED 50MG	6155/22T	022369	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
EPLERENONE ACCORD TABLET, FILM COATED 25MG	6156/22T	022368	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MEDOFLUCON CAPSULE, HARD 200MG	7078/22T, 7079/22T	019830	MEDOCHEMIE LTD	B.II.b.z B.II.b.z - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Other variation B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms
MEDOFLUCON CAPSULE, HARD 150MG	7076/22T, 7077/22T	012701	MEDOCHE MIE LTD	B.II.b.z B.II.b.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Other variation B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms
MEDOFLUCON CAPSULE, HARD 50MG	7080/22T, 7081/22T	012700	MEDOCHE MIE LTD	B.II.b.z B.II.b.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Other variation B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms
ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 40MG	8290/22T, 8291/22T, 8292/22T, 8293/22T, 8294/22T, 8295/22T	020971	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 20MG	8296/22T, 8297/22T, 8298/22T, 8299/22T, 8300/22T, 8301/22T	020970	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
CONTRACTUBEX GEL	8744/22T, 8745/22T	005509	MERZ PHARMACEUTICALS GMBH	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/int

				ermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.II.d.2.f B.II.d.2.f - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - To reflect compliance with the Ph.Eur. and remove reference to the outdated internal test method and test method number*
ZOBRAL TABLET, FILM COATED 5MG	8476/22T	021149	DELORBIS PHARMACEUTICALS LTD	B.II.f.z B.II.f.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Other variation
GRACIAL TABLET	8712/22T	018377	ASPEN PHARMA TRADING LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
KIVALA TABLET, FILM COATED	8399/22T	022346	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TAKS TABLET, GASTRO-RESISTANT 50MG	8131/22T	019839	CODAL-SYNTO LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
CLOMIPRAMINE TABLET, FILM COATED 25MG	8450/22T, 8451/22T, 8452/22T	014386	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w
ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	2907/22T	023141	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	2908/22T	023142	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	2910/22T	023144	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	2909/22T	023143	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
CARAMLO TABLET 5MG/8MG	7594/22T	022063	ZENTIVA K.S.	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
CARAMLO TABLET 10MG/16MG	7595/22T	022064	ZENTIVA K.S.	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
CEFAZOLIN/NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G/VIAL	2957/22T	023010	NORIDEM ENTERPRISES LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CEFAZOLIN/NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	2956/22T	023009	NORIDEM ENTERPRISES LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CEFAZOLIN/NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G/VIAL	7387/22T	023010	NORIDEM ENTERPRISES LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
CEFAZOLIN/NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	7386/22T	023009	NORIDEM ENTERPRISES LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
TIORESP INHALATION POWDER, PRE-DISPENSED 10MCG/DOSE	8337/22T	023586	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate

				from an already approved manufacturer
SEDALOR SOLUTION FOR INJECTION OR INFUSION 2MG/10ML AMP	3198/22T, 3199/22T, 3200/22T, 3201/22T	022315	DR. FRANZ KOHLER CHEMIE GMBH	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate

TEMELOR TABLET 0.5MG	6178/22T	023627	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TEMELOR TABLET 2.5MG	6176/22T	023629	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TEMELOR TABLET 1MG	6177/22T	023628	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZETIRAF TABLET 10MG	3146/21T	022787	RAFARM S.A.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LEVOFLOXACIN/RAFARM [PF] EYE DROPS, SOLUTION 5MG/ML	7385/22T	023328	RAFARM S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NOPRILAM DT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	7884/22T, 7885/22T	019090	BIAL-PORTELA & CA, SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
TEVETEN TABLET, FILM COATED 600MG	8338/22T, 8339/22T	019260	MYLAN IRE HEALTHCARE LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or

				addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CITRAFLEET POWDER FOR ORAL SOLUTION	7776/21T	022389	CASEN RECORDATI SL	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 40MG	7074/22T	020994	TAD PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 20MG	7075/22T	020993	TAD PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NUTRIFLEX OMEGA PERI EMULSION FOR INFUSION	5355/22T, 5356/22T, 5357/22T, 5358/22T, 5359/22T	023385	B. BRAUN MELSUNGEN AG	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - Eur A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
VIZITRAV EYE DROPS, SOLUTION 40MCG/ML	5023/22T	023221	BAUSCH + LOMB IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPOPEN TABLET, FILM COATED 5MG/10MG	5665/22T, 5666/22T	023318	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LIPOPEN TABLET, FILM COATED 40MG/10MG	5659/22T, 5660/22T	023321	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the

				active substance - Minor changes to an approved test procedure
LIPOPEN TABLET, FILM COATED 20MG/10MG	5661/22T, 5662/22T	023320	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LIPOPEN TABLET, FILM COATED 10MG/10MG	5663/22T, 5664/22T	023319	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
TIENAM POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	5190/22T	021719	MERCK SHARP & DOHME BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	7185/22T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes
INDOREM CAPSULE, HARD 25MG	8615/22T	007732	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
PRIAXEN TABLET 500MG	8386/22T	012479	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
PRIAXEN TABLET 250MG	8387/22T	010350	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	7963/21T, 7964/21T	023275	VIATRIS HEALTHCARE LIMITED.	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - New certificate for a starting mater
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	7961/21T, 7962/21T	023276	VIATRIS HEALTHCARE LIMITED.	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient -

				European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - New certificate for a starting mater
QLAIRA TABLET, FILM COATED	2592/22T	020525	BAYER HELLAS ABEE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
IMATINIB/MYLAN TABLET, FILM COATED 400MG	7400/22T, 7401/22T	023473	MYLAN PHARMACEUTICALS LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
IMATINIB/MYLAN TABLET, FILM COATED 100MG	7402/22T, 7403/22T	023472	MYLAN PHARMACEUTICALS LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

				A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	7040/22T	023275	VIATRIS HEALTHCARE LIMITED.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	7039/22T	023276	VIATRIS HEALTHCARE LIMITED.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
TEMELOR TABLET 1MG	5413/22T, 5414/22T	023628	MEDOCHEMIE LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TEMELOR TABLET 2.5MG	5411/22T, 5412/22T	023629	MEDOCHEMIE LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TEMELOR TABLET 0.5MG	5415/22T, 5416/22T	023627	MEDOCHEMIE LTD	B.II.b.2.a B.II.b.2.a -

				QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
LEKAP TABLET, FILM COATED 100MG	4504/22T, 4505/22T	021306	JUBILANT PHARMACEUTICALS NV	B.III.z B.III.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Other variation B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LEKAP TABLET, FILM COATED 25MG	4500/22T, 4501/22T	021304	JUBILANT PHARMACEUTICALS NV	B.III.z B.III.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Other variation B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LEKAP TABLET, FILM COATED 50MG	4502/22T, 4503/22T	021305	JUBILANT PHARMACEUTICALS NV	B.III.z B.III.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Other variation B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BONDAPEN TABLET, FILM COATED 35MG	3606/20T	021124	ELPEN PHARMACEUTICAL CO INC	B.II.d.2 a) Minor changes to an approved test procedure
ALFOXAN CAPSULE, HARD 250MG	8182/22T	019924	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALFOXAN 500 TABLET, FILM COATED 500MG	8180/22T	014417	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALFOXAN SYRUP 50MG/5ML	8181/22T	016070	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance

				For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MELGESIC TABLET 15MG	8071/22T	019758	DELORBIS PHARMACEUTICALS LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
MELGESIC TABLET 7.5MG	8072/22T	019759	DELORBIS PHARMACEUTICALS LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR

				or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
VIZITRAV EYE DROPS, SOLUTION 40MCG/ML	6120/22T, 6121/22T	023221	BAUSCH + LOMB IRELAND LIMITED	B.II.e.7.a B.II.e.7.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Change in the name of a supplier of a packaging component. If the information is not needed in the dossier CMDh recommends deletion of this information. B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
GLYFORMIN TABLET, FILM COATED 500MG	4882/22T	009028	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GLYFORMIN TABLET, FILM COATED 850MG	4881/22T	016606	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DAREQ TABLET, FILM COATED 5MG	8070/22T	021529	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
ABIRATERONE SAPIENS TABLET, FILM COATED 500MG	8106/22T	023636	SAPIENS PHARMACEUTICALS LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT -

				Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
NOCDURNA ORAL LYOPHILISATE 50MCG	2564/22T	022544	FERRING HELLAS MEPE	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
NOCDURNA ORAL LYOPHILISATE 50MCG	2564/22T	022544	FERRING HELLAS MEPE	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
NOCDURNA ORAL LYOPHILISATE 25MCG	2563/22T	022543	FERRING HELLAS MEPE	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
NOCDURNA ORAL LYOPHILISATE 25MCG	2563/22T	022543	FERRING HELLAS MEPE	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (MULTIPLE DOSES)	7693/22T	022888	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
YASMINELLE TABLET, FILM COATED 0.02MG/3MG	7684/22T	020125	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
YASMIN TABLET, FILM COATED 0.03MG/3MG	7685/22T	022847	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/VIAL (100IU/ML)	7675/22T, 7676/22T, 7677/22T, 7678/22T, 7679/22T, 7680/22T, 7681/22T, 7682/22T, 7683/22T	020943	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or am B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or

				limits of the immediate packagin B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/VIAL(100IU/ML)	7666/22T, 7667/22T, 7668/22T, 7669/22T, 7670/22T, 7671/22T, 7672/22T, 7673/22T, 7674/22T	020944	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or am B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED

				PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible
VOLTAREN SUPPOSITORY 50MG	7896/22T	018443	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
VOLTAREN FOR CHILDREN SUPPOSITORY 12.5MG	7897/22T	018454	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
VOLTAREN TABLET, GASTRO-RESISTANT 50MG	7901/22T	018455	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation

VOLTAREN SUPPOSITORY 100MG	7895/22T	018400	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
VOLTAREN SR SUSTAINED RELEASE TABLETS 75MG	7900/22T	018459	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
VOLTAREN D TABLET, DISPERSIBLE 50MG	7894/22T	018457	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
VOLTAREN INJECTION 75MG/3ML	7898/22T	018434	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
VOLTAREN RETARD SUSTAINED RELEASE TABLETS 100MG	7899/22T	018444	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal

				products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
LIPITOR TABLET, FILM COATED 20MG	5087/22T	019490	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, FILM COATED 10MG	5088/22T	019489	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INSPRA TABLET, FILM COATED 25MG	5081/22T	020103	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INSPRA TABLET, FILM COATED 50MG	5080/22T	020104	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, FILM COATED 40MG	5086/22T	019491	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEURONTIN CAPSULE, HARD 300MG	5079/22T	017445	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEURONTIN CAPSULE, HARD 400MG	5078/22T	017446	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	5074/22T	018335	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, CHEWABLE 20MG	5084/22T	020729	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EFEXOR XR PROLONGED RELEASE CAPSULES 37.5MG	5075/22T	020345	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NORVASC CAPSULE, HARD 5MG	5090/22T	013774	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DETRUSITOL TABLET, FILM COATED 2MG	5076/22T	023122	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CELEBREX CAPSULE, HARD 200MG	5082/22T	023173	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, CHEWABLE 10MG	5085/22T	020728	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NORVASC CAPSULE, HARD 10MG	5089/22T	013775	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CELEBREX CAPSULE, HARD 100MG	5083/22T	023174	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE

				CHANGES - Change in the name and/or address of the marketing authorisation holder
XALATAN EYE DROPS, SOLUTION 50MCG/ML	5077/22T	020805	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MOXICLAV POWDER FOR ORAL SUSPENSION 156.25MG/5ML	6901/22T	017076	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MOXICLAV FORTE POWDER FOR ORAL SUSPENSION 312,5MG/5ML	6900/22T	017075	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which

				no new additional data is required to be submitted by the MAH
LANSO GASTRO-RESISTANT CAPSULE, HARD 30MG	7631/22T	020737	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
EUTHYROX TABLET 50MCG	8224/22T	019425	MERCK A E HELLAS	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EUTHYROX TABLET 100MCG	8223/22T	019426	MERCK A E HELLAS	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	7976/22T	022399	ALLERGAN PHARMACEUTICALS IRELAND	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	7975/22T	022400	ALLERGAN PHARMACEUTICALS IRELAND	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	7974/22T	022401	ALLERGAN PHARMACEUTICALS IRELAND	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 25MG	7956/22T, 7957/22T, 7958/22T, 7959/22T	023253	PHARMASCIENCE INTERNATIONAL LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of

				specification limits B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 5MG	7968/22T, 7969/22T, 7970/22T, 7971/22T	023250	PHARMASCIENCE INTERNATIONAL LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing

				process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 15MG	7960/22T, 7961/22T, 7962/22T, 7963/22T	023252	PHARMASCIENCE INTERNATIONAL LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the

				manufacturing process
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 10MG	7964/22T, 7965/22T, 7966/22T, 7967/22T	023251	PHARMASCIENCE INTERNATIONAL LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
ODELO TABLET, FILM COATED 10MG	8089/22T	023596	ELPEN PHARMACEUTICAL CO INC	B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of

				excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
ODELO TABLET, FILM COATED 15MG	8088/22T	023597	ELPEN PHARMACEUTICAL CO INC	B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
ODELO TABLET, FILM COATED 2.5MG	8090/22T	023595	ELPEN PHARMACEUTICAL CO INC	B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
ODELO TABLET, FILM COATED 20MG	8087/22T	023598	ELPEN PHARMACEUTICAL CO INC	B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
MEDICORT TABLET 4MG	4448/22T, 4449/22T, 4450/22T	023495	MEDICAIR BIOSCIENCE LABORATOR	C.I.8.a C.I.8.a - SAFETY, EFFICACY,

			IES CY LIMITED	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MEDICORT TABLET 8MG	4445/22T, 4446/22T, 4447/22T	023496	MEDICAIR BIOSCIENCE LABORATORIES CY LIMITED	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the

				Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MEDICORT TABLET 20MG	4442/22T, 4443/22T, 4444/22T	023497	MEDICAIR BIOSCIENCE LABORATORIES CY LIMITED	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Other variation
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	7295/22T	020233	IBSA FARMACEUTICI ITALIA SRL	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	7295/22T	020233	IBSA FARMACEUTICI ITALIA SRL	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	7292/22T	021777	IBSA FARMACEUTICI ITALIA SRL	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of

				pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	7292/22T	021777	IBSA FARMACEUTICI ITALIA SRL	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	7294/22T	020234	IBSA FARMACEUTICI ITALIA SRL	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance

				System Master File (PSMF) location
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	7294/22T	020234	IBSA FARMACEUTICI ITALIA SRL	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	7293/22T	021778	IBSA FARMACEUTICI ITALIA SRL	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	7293/22T	021778	IBSA FARMACEUTICI ITALIA SRL	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of

				pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/12.5MG	7878/22T, 7879/22T	023590	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/25MG	7876/22T, 7877/22T	023591	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/25MG	7872/22T, 7873/22T	023593	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/320MG/25MG	7870/22T, 7871/22T	023594	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate

				from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/12.5MG	7874/22T, 7875/22T	023592	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	1738/22T	019724	MERCK SHARP & DOHME BV	B.II.a.3.b.1 B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients
INFANRIX TETRA SUSPENSION FOR INJECTION	6443/21T, 6444/21T, 6445/21T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DEXMEDETOMIDINE/KABI CONCENTRATE FOR SOLUTION FOR INFUSION 100MCG/ML	6850/22T	023551	FRESENIUS KABI HELLAS A.E.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RITONAVIR ACCORD TABLET, FILM COATED 100MG	5705/22T	022801	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CERTICAN TABLET 0.25MG	5654/22T	019642	NOVARTIS IRELAND LIMITED	B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation

CERTICAN TABLET 1MG	5653/22T	019645	NOVARTIS IRELAND LIMITED	B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
CERTICAN TABLET 0.5MG	5652/22T	019643	NOVARTIS IRELAND LIMITED	B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
CERTICAN TABLET 0.75MG	5651/22T	019644	NOVARTIS IRELAND LIMITED	B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
SORIL THROAT SPRAY OROMUCOSAL SPRAY, SOLUTION 1.5MG/ML	8060/22T, 8061/22T, 8062/22T, 8063/22T	023434	SAPIENS PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting B.II.b.2.a B.II.b.2.a - QUALITY

				CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia
FLEXBUMIN SOLUTION FOR INFUSION 200G/L	6268/22T	020477	BAXALTA INNOVATIONS GMBH	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
FLEXBUMIN SOLUTION FOR INFUSION 250G/L	6267/22T	020478	BAXALTA INNOVATIONS GMBH	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such

				as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
ULTRAVIST 370 SOLUTION FOR INJECTION 76.9%	654/21T	018966	BAYER HELLAS ABEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ULTRAVIST 300 SOLUTION FOR INJECTION 62.34%	655/21T	023211	BAYER HELLAS ABEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	9368/21T	020252	GLAXOSMITHKLINE BIOLOGICALS SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CLOPIDOGREL ACCORD TABLET, FILM COATED 75MG	7321/22T	021757	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PAZOCTAM POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/ VIAL	6581/22T, 6582/22T	022811	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.z B.I.z - Quality change - Active substance - Other variation
IMODIUM ORIGINAL CAPSULE, HARD 2MG	8347/22T	006139	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
LENALIDOMIDE STADA CAPSULE, HARD 5MG	7502/22T	023619	STADA ARZNEIMITTEL AG	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active

				substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LENALIDOMIDE STADA CAPSULE, HARD 2.5MG	7501/22T	023618	STADA ARZNEIMITTEL AG	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LENALIDOMIDE STADA CAPSULE, HARD 10MG	7504/22T	023621	STADA ARZNEIMITTEL AG	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LENALIDOMIDE STADA CAPSULE, HARD 7.5MG	7503/22T	023620	STADA ARZNEIMITTEL AG	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LENALIDOMIDE STADA CAPSULE, HARD 20MG	7506/22T	023623	STADA ARZNEIMITTEL AG	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LENALIDOMIDE STADA CAPSULE, HARD 25MG	7507/22T	023624	STADA ARZNEIMITTEL AG	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LENALIDOMIDE STADA CAPSULE, HARD 15MG	7505/22T	023622	STADA ARZNEIMITTEL AG	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FLIXOTIDE EVOHALER 125MCG	5127/22T, 5128/22T	016809	GLAXOSMITHKLINE	B.I.b.1.c B.I.b.1.c - QUALITY

			(IRELAND) LIMITED	CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/100MCG	5131/22T, 5132/22T	022630	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing

				process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/250MCG	5133/22T, 5134/22T	022631	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/500MCG	5135/22T, 5136/22T	022632	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient -

				European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLIXOTIDE EVOHALER 50MCG	5129/22T, 5130/22T	016810	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
STILNOX TABLET, FILM COATED 10MG	8000/20T	019612	SANOFI-AVENTIS GROUPE	C.I.4 Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
EMLA CREAM 5%	1976/22T	012900	ASPEN PHARMA TRADING LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
BONAMENS SOLUTION FOR INJECTION IN A PRE-FILLED PEN 20µg/80µl	7299/22T, 7300/22T	023573	ELPEN PHARMACEUTICAL CO INC	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate

				packaging of the finished product - Other changes to a test procedure (including replacement or addition)
DONEPEZIL KRKA TABLET, FILM COATED 5MG	4551/22T	021435	KRKA D.D. NOVO MESTO	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
DONEPEZIL KRKA TABLET, FILM COATED 10MG	4550/22T	021436	KRKA D.D. NOVO MESTO	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
SIDIPAST TABLET, FILM COATED 90MG	3656/22T, 3657/22T	023186	DEMO S.A.	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.c.2.a B.I.c.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the active substance -

				Tightening of specification limits
SIDIPAST TABLET, FILM COATED 180MG	3658/22T, 3659/22T	023187	DEMO S.A.	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.c.2.a B.I.c.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the active substance - Tightening of specification limits
SIDIPAST TABLET, FILM COATED 360MG	3660/22T, 3661/22T	023188	DEMO S.A.	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.c.2.a B.I.c.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in

				the specification parameters and/or limits of the immediate packaging of the active substance - Tightening of specification limits
SIDIPAST TABLET, FILM COATED 90MG	3247/22T	023186	DEMO S.A.	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
SIDIPAST TABLET, FILM COATED 180MG	3248/22T	023187	DEMO S.A.	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
SIDIPAST TABLET, FILM COATED 360MG	3249/22T	023188	DEMO S.A.	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully

				comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
ALBUMEON SOLUTION FOR INFUSION 200G/l	2696/22T, 2697/22T	022388	CSL BEHRING GMBH	B.I.a.4.b B.I.a.4.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Addition of a new in-process test and limits B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
NITRAZEPAM ACCORD TABLET 5MG	8097/22T	022397	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FULVESTRANT PHARMASCIENCE	2462/22T	23287	PHARMASCIENCE	B.II.b.2.a B.II.b.2.a -

SOLUTION FOR INJECTION IN PREFILLED SYRINGES 250MG			INTERNATIONAL LTD	QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
MINAXEN CAPSULE, HARD 50MG	8107/22T	016540	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DEXAMETHASONE/RAFARM [PF] EYE DROPS, SOLUTION 1MG/ML	1318/22T	023006	RAFARM S.A.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including

				contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	9749/21T	023616	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	9009/21T, 9010/21T, 9011/21T, 9012/21T	018335	UPJOHN HELLAS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification

				parameter (e.g. dele B.I.b.2.b B.I.b.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/ intermedia
EFEXOR XR PROLONGED RELEASE CAPSULES 37.5MG	9005/21T, 9006/21T, 9007/21T, 9008/21T	020345	UPJOHN HELLAS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele B.I.b.2.b B.I.b.2.b -

				QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/ intermedia
VENLAFAXINE/UPJOHN CAPSULE, HARD, PROLONGED-RELEASE 75MG	9021/21T, 9022/21T, 9023/21T, 9024/21T	022381	UPJOHN HELLAS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele B.I.b.2.b B.I.b.2.b - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/ intermedia
VENLAFAXINE/UPJOHN CAPSULE, HARD, PROLONGED-RELEASE 150MG	9017/21T, 9018/21T, 9019/21T, 9020/21T	022382	UPJOHN HELLAS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele B.I.b.2.b B.I.b.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance -

				Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/ intermedia
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	9013/21T, 9014/21T, 9015/21T, 9016/21T	018334	UPJOHN HELLAS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele B.I.b.2.b B.I.b.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or

				starting material/reagent/intermediate used in the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/ intermedia
VENLAFAXINE/UPJOHN CAPSULE, HARD, PROLONGED-RELEASE 37.5MG	9025/21T, 9026/21T, 9027/21T, 9028/21T	022380	UPJOHN HELLAS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele B.I.b.2.b B.I.b.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in

				the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/ intermedia
DAONIL TABLET 5MG	6260/22T	000655	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETASERC TABLET, ORODISPERSIBLE 24MG	4881/21T, 4882/21T	022394	MYLAN IRE HEALTHCARE LIMITED	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
BETASERC TABLET, ORODISPERSIBLE 24MG	3914/21T	022394	MYLAN IRE HEALTHCARE LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 22.5MG	5568/22T	019686	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure

				concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 7.5MG	5569/22T	019687	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 45MG	5567/22T	020460	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the

				outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
QUETRA TABLET, FILM COATED 1000MG	6740/22T	021011	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
QUETRA TABLET, FILM COATED 750MG	6741/22T	021010	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur.

				Monograph - Updated certificate from an already approved manufacturer
QUETRA TABLET, FILM COATED 500MG	6742/22T	021009	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
QUETRA TABLET, FILM COATED 250MG	6743/22T	021008	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

CLIFT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	8086/22T	022666	MYLAN IRELAND LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
OXYNORM CAPSULE, HARD 5MG	8049/22T	020304	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
OXYNORM CAPSULE, HARD 10MG	8047/22T	020306	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
OXYNORM CAPSULE, HARD 20MG	8048/22T	020305	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G	3861/22T	20649	FRESENIUS KABI HELLAS AE	B.II.b.1.c B.II.b.1.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site

				for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	3862/22T	20650	FRESENIUS KABI HELLAS AE	B.II.b.1.c B.II.b.1.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes
VIDEL TABLET 50MG	6964/22T	023400	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
ARTHRINAL TABLET, FILM COATED 20MG	7841/22T	020028	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
MEZAVANT GASTRO-RESISTANT, PROLONGED RELEASE TABLETS 1200MG	9166/21T	020250	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VIBRAMYCIN TABLET, DISPERSIBLE 100MG	4649/22T	013023	PFIZER HELLAS AE	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	7049/22T	020032	ALLERGAN PHARMACEUTICALS IRELAND	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	4273/22T, 4274/22T	020881	ASTRAZENECA AB	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
SYMBICORT TURBUHALER POWDER FOR INHALATION 320MCG/9MCG	4271/22T, 4272/22T	020882	ASTRAZENECA AB	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5MCG	4262/22T, 4263/22T	020883	ASTRAZENECA AB	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in

				the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
LIDOCAINE ACCORD SOLUTION FOR INJECTION 20MG/ML	6916/22T	022383	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LIDOCAINE ACCORD SOLUTION FOR INJECTION 10MG/ML	6917/22T	022377	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	5162/22T	020881	ASTRAZENECA AB	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the

				finished product - Up to 10-fold compared to the originally approved batch size
SYMBICORT TURBUHALER POWDER FOR INHALATION 320MCG/9MCG	5163/22T	020882	ASTRAZENECA AB	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
ATAZANAVIR ACCORD CAPSULE, HARD 300MG	5182/22T	023147	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ATAZANAVIR ACCORD CAPSULE, HARD 150MG	5183/22T	023146	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 22.5MG	944/22T, 945/22T, 946/22T, 947/22T, 948/22T, 949/22T, 950/22T, 951/22T, 952/22T, 953/22T, 954/22T, 955/22T, 2837/22T, 2838/22T, 2839/22T, 2840/22T, 2841/22T,	019686	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	B.IV.1.c B.IV.1.c - QUALITY CHANGES - Medical Devices - Change of a measurin B.II.b.3.b B.II.b.3.b

	2842/22T, 2843/22T, 2844/22T, 2845/22T, 2846/22T, 2847/22T, 2848/22T			- QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - R A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an ac B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of fini B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of fini B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of fini C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.5.b B.II.b.5.b - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - C
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 7.5MG	956/22T, 957/22T, 958/22T, 959/22T, 960/22T, 961/22T, 962/22T, 963/22T, 964/22T, 965/22T, 966/22T, 967/22T, 2849/22T, 2850/22T, 2851/22T, 2852/22T, 2853/22T, 2854/22T, 2855/22T, 2856/22T, 2857/22T, 2858/22T, 2859/22T, 2860/22T	019687	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	B.IV.1.c B.IV.1.c - QUALITY CHANGES - Medical Devices - Change of a measurin B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - R A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an ac B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of fini B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of fini B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of fini C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - C B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 45MG	932/22T, 933/22T, 934/22T, 935/22T, 936/22T, 937/22T, 938/22T, 939/22T, 940/22T, 941/22T, 942/22T, 943/22T, 2825/22T, 2826/22T, 2827/22T, 2828/22T, 2829/22T, 2830/22T, 2831/22T, 2832/22T, 2833/22T, 2834/22T, 2835/22T, 2836/22T	020460	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	B.IV.1.c B.IV.1.c - QUALITY CHANGES - Medical Devices - Change of a measurin B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - R A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an ac B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of fini B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of fini B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of fini C.I.11.b C.I.11.b -

				SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C
PACLITAXEL ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	3525/22T, 3526/22T	020838	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
VOLTAREN OPHTHA EYE DROPS 0.1%	8361/22T	013462	LABORATOIRES THEA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VIDEL TABLET 50MG	6472/22T	023400	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
RIDOCA CAPSULE, HARD 180MG	7147/22T, 7148/22T, 7149/22T, 7150/22T	022134	AENORASIS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Updated certificate from an already B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Deletion of certificates (in case mu
RIDOCA CAPSULE, HARD 5MG	7163/22T, 7164/22T, 7165/22T, 7166/22T	022130	AENORASIS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Updated certificate from an already B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Deletion of certificates (in case mu
RIDOCA CAPSULE, HARD 20MG	7159/22T, 7160/22T, 7161/22T, 7162/22T	022131	AENORASIS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Updated certificate from an already B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Deletion of certificates (in case mu
RIDOCA CAPSULE, HARD 140MG	7151/22T, 7152/22T, 7153/22T, 7154/22T	022133	AENORASIS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Deletion of certificates (in case mu
RIDOCA CAPSULE, HARD 250MG	7143/22T, 7144/22T, 7145/22T, 7146/22T	022135	AENORASIS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting

				material/reagent/ intermediate/or excipient - Deletion of certificates (in case mu
RIDOCA CAPSULE, HARD 100MG	7155/22T, 7156/22T, 7157/22T, 7158/22T	022132	AENORASIS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Deletion of certificates (in case mu

DAPTOMYCIN NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	4557/22T, 4558/22T, 4559/22T	023323	NORIDEM ENTERPRISES LTD	B.II.b.4.d B.II.b.4.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
DAPTOMYCIN NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 350MG/VIAL	4560/22T, 4561/22T, 4562/22T	023322	NORIDEM ENTERPRISES LTD	B.II.b.4.d B.II.b.4.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex

				manufacturing processes B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
HEMOSOL B0 SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS	1926/22T, 1927/22T	023511	BAXTER HOLDING B.V.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
REGIOCIT SOLUTION FOR HAEMOFILTRATION	1924/22T, 1925/22T	022304	BAXTER HOLDING B.V.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DAKTACORT 2%/1% W/W CREAM	7941/22T	007082	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
REFETIB TABLET, FILM COATED 250MG	8270/22T	022848	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
REFETIB TABLET, FILM COATED 250MG	6627/22T	022848	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MOXILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	7012/22T	012961	MEDOCHEMIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
MOXILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	7013/22T	012960	MEDOCHEMIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
DELIPOST TABLET, FILM COATED 10MG	6592/22T	021915	RAFARM S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product -

				Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DELIPOST TABLET, FILM COATED 20MG	6591/22T	021916	RAFARM S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DELIPOST TABLET, FILM COATED 40MG	6590/22T	021917	RAFARM S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MUCOFALK ORANGE GRANULES FOR ORAL SUSPENSION 3.25G/5G SACHET	8124/22T	007597	DR. FALK PHARMA GMBH	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
MYELOMIDE CAPSULE, HARD 25MG	5987/22T	023185	ANABIOSIS PC.	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
MYELOMIDE CAPSULE, HARD 10MG	5989/22T	023183	ANABIOSIS PC.	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
MYELOMIDE CAPSULE, HARD 15MG	5988/22T	023184	ANABIOSIS PC.	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
OMNIC MODIFIED-RELEASE CAPSULE, HARD 0.4MG	4352/22T	022169	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
OMNIC TOCAS TABLET, PROLONGED-RELEASE 0.4MG	4351/22T	022184	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
OMNIC MODIFIED-RELEASE CAPSULE, HARD 0.4MG	4340/22T	022169	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
OMNIC TOCAS TABLET, PROLONGED-RELEASE 0.4MG	4339/22T	022184	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TAVANIC TABLET, FILM COATED 500MG	5142/21T	019283	SANOFI-AVENTIS GROUPE	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
NORVASC CAPSULE, HARD 5MG	5566/22T	013774	UPJOHN HELLAS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
NORVASC CAPSULE, HARD 10MG	5565/22T	013775	UPJOHN HELLAS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
BELKYRA SOLUTION FOR INJECTION 10MG/ML	7977/22T	022647	ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED (APIL)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
GLYFORMIN TABLET, FILM COATED 500MG	8715/21T, 8716/21T	009028	REMEDICA LTD	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test

				method as a result of a safety or quality issue B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
GLYFORMIN TABLET, FILM COATED 850MG	8713/21T, 8714/21T	016606	REMEDICA LTD	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
ROSUVASTATIN ACINO TABLET, FILM COATED 40MG	7753/22T	022941	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROSUVASTATIN ACINO TABLET, FILM COATED 5MG	7756/22T	022938	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROSUVASTATIN ACINO TABLET, FILM COATED 20MG	7754/22T	022940	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal

				products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROSUVASTATIN ACINO TABLET, FILM COATED 10MG	7755/22T	022939	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BETAISODONA CREAM 5% W/W	8356/22T	014789	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
CISATRACURIUM ACCORDPHARMA SOLUTION FOR INJECTION OR INFUSION 2MG/ML	8391/21T	023378	ACCORD HEALTHCARE S.L.U	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or

				limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	3583/21T	022399	ALLERGAN PHARMACEUTICALS IRELAND	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	3584/21T	022400	ALLERGAN PHARMACEUTICALS IRELAND	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	3585/21T	022401	ALLERGAN PHARMACEUTICALS IRELAND	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality,

				preclinical, clinical or pharmacovigilance data
FINGOLIMOD SAPIENS CAPSULE, HARD 0.5MG	8275/22T	023653	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LOSAR PLUS TABLET, FILM COATED 50MG/12.5MG	7603/22T, 7604/22T, 7605/22T, 7606/22T, 7607/22T	020782	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.III.1.a.4 B.III.1.a.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active

				substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharm
TOSTRAN GEL 2%	6224/22T, 6225/22T, 6226/22T	022871	KYOWA KIRIN HOLDINGS B.V.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
MEDOVIR TABLET 800MG	8455/22T, 8456/22T, 8457/22T	014928	MEDOCHEMIE LTD	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
MEDOVIR TABLET 200MG	8461/22T, 8462/22T, 8463/22T	012781	MEDOCHE MIE LTD	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
MEDOVIR TABLET 400MG	8458/22T, 8459/22T, 8460/22T	014927	MEDOCHE MIE LTD	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
DEXATON ORAL SOLUTION 2MG/5ML	6781/22T	021792	VIANEX S.A	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

ZAFIBRAL TABLET, FILM COATED 200MG	8112/22T	013763	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROPIVACAINE KABI SOLUTION FOR INJECTION 2MG/ML	54/22T	021421	FRESENIUS KABI HELLAS A.E.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
ROPIVACAINE KABI SOLUTION FOR INJECTION 7.5MG/ML	53/22T	021424	FRESENIUS KABI HELLAS A.E.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture -

				Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
ROPIVACAINE KABI SOLUTION FOR INJECTION 10MG/ML	52/22T	021425	FRESENIUS KABI HELLAS A.E.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
ROPIVACAINE KABI SOLUTION FOR INFUSION 2MG/ML	50/22T	021422	FRESENIUS KABI HELLAS A.E.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing

				process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
ROPIVACAINE KABI SOLUTION FOR INJECTION 5MG/ML	51/22T	021423	FRESENIUS KABI HELLAS A.E.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
RADICUT TABLET, FILM COATED 50MG/1000MG	5772/22T	023721	GENEPHARM SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
RADICUT TABLET, FILM COATED 50MG/850MG	5773/22T	023720	GENEPHARM SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF

OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/25MG	7950/22T	023160	MYLAN IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/12.5MG	7952/22T	023158	MYLAN IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
OLMEDIPIN PLUS TABLET, FILM COATED 20MG/5MG/12.5MG	7954/22T	023156	MYLAN IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/12.5MG	7953/22T	023157	MYLAN IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/25MG	7951/22T	023159	MYLAN IRELAND LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
CATAFLAM TABLET, COATED 50MG	7955/22T	018492	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation

FINRINA CAPSULE, HARD 0.5MG	7845/22T	023582	GENEPHARM SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VALSIMIA TABLET, FILM COATED 10MG/160MG	7522/22T	022441	ELPEN PHARMACEUTICAL CO INC	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
VALSIMIA TABLET, FILM COATED 5MG/80MG	7524/22T	022439	ELPEN PHARMACEUTICAL CO INC	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk

				management plan - Implementation of wording agreed by the competent authority
VALSIMIA TABLET, FILM COATED 5MG/160MG	7523/22T	022440	ELPEN PHARMACEUTICAL CO INC	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
NORVASC CAPSULE, HARD 5MG	6360/22T	013774	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NORVASC CAPSULE, HARD 10MG	6359/22T	013775	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LEVOFLOXACIN KABI SOLUTION FOR INFUSION 5MG/ML	5941/22T	20574	FRESENIUS KABI HELLAS AE	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
PULMOTON INHALATION POWDER, PRE-DISPENSED (100+6) MCG/DOSE	7259/22T, 7260/22T	021864	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.b B.I.b.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/intermediate, if an alternative test procedure is already authorised. B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

				Updated certificate from an already approved manufacturer
PULMOTON INHALATION POWDER, PRE-DISPENSED (400+12) MCG/DOSE	7255/22T, 7256/22T	021866	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.b B.I.b.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/intermediate, if an alternative test procedure is already authorised. B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PULMOTON INHALATION POWDER, PRE-DISPENSED (200+6) MCG/DOSE	7257/22T, 7258/22T	021865	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.b B.I.b.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active

				substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/intermediate, if an alternative test procedure is already authorised. B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TOLTERANA PROLONGED RELEASE CAPSULES 2MG	6287/22T, 6288/22T, 6289/22T, 6290/22T, 6291/22T, 6292/22T, 6293/22T, 6294/22T, 6295/22T	021911	PHARMATHEN S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia
TOLTERANA PROLONGED RELEASE CAPSULES 4MG	6296/22T, 6297/22T, 6298/22T, 6299/22T, 6300/22T, 6301/22T, 6302/22T, 6303/22T, 6304/22T	021912	PHARMATHEN S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia
ASPRO CLEAR EFFERVESCENT TABLET 300MG	5249/22T	022932	BAYER HELLAS ABEE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TOLTERANA PROLONGED RELEASE CAPSULES 2MG	5930/22T, 7763/22T	021911	PHARMATHEN S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TOLTERANA PROLONGED RELEASE CAPSULES 4MG	5929/22T, 7762/22T	021912	PHARMATHEN S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TEZOL TABLET, GASTRO-RESISTANT 100MG	8102/22T	023437	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of

				change(s) for which no new additional data is required to be submitted by the MAH
REMABIRAT TABLET, FILM COATED 1000MG	7192/21T	023507	REMEDICA LTD	C.I.6.b C.I.6.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication
REFENTA POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION 1MG	8125/22T, 8126/22T	022214	SAPIENS PHARMACEUTICALS LTD	B.II.g.5.b B.II.g.5.b - QUALITY CHANGES - FINISHED PRODUCT - Design Space and post approval change management protocol - Implementation of changes foreseen in an approved change management protocol - The implementation of the change requires further supportive data
ZOVIRAX CREAM 5% W/W	6309/22T, 6310/22T	009376	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product,

				packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
IVIVERZ TABLET, FILM COATED 600MG/300MG	8050/22T	022685	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MELGESIC TABLET 15MG	7533/22T	019758	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional

				data is required to be submitted by the MAH
MELGESIC TABLET 7.5MG	7534/22T	019759	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VAGIFEM FILM COATED VAGINAL TABLETS 10MCG	1263/22T	020906	NOVO NORDISK A/S	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update

DUSPATALIN RETARD CAPSULE, HARD, PROLONGED-RELEASE 200MG	7058/22T, 7059/22T, 7060/22T	016991	MYLAN IRE HEALTHCAR E LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
DUSPATALIN TABLET, COATED 135MG	7055/22T, 7056/22T, 7057/22T	009670	MYLAN IRE HEALTHCAR E LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int ermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	5154/22T	023151	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	5155/22T	023150	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	5156/22T	023149	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	5157/22T	023148	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which

				no new additional data is required to be submitted by the MAH
FODREN TABLET, GASTRO-RESISTANT 10MG	7865/22T	021181	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FODREN TABLET, GASTRO-RESISTANT 20MG	7864/22T	021182	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
PARIET TABLET, GASTRO-RESISTANT 10MG	7861/22T	018887	JANSSEN-CILAG INTERNATIONAL NV	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PARIET TABLET, GASTRO-RESISTANT 20MG	7862/22T	018888	JANSSEN-CILAG INTERNATIONAL NV	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

TESTOGEL GEL 50MG	4356/22T	020520	LABORATOIRES BESINS INTERNATIONAL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TESTOGEL GEL 25MG	4357/22T	020590	LABORATOIRES BESINS INTERNATIONAL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ALBUREX 5 SOLUTION FOR INFUSION 50G/L	1371/22T	20629	CSL BEHRING GMBH	B.I.d.1.b.3 B.I.d.1.b.3 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Storage conditions - Change in storage conditions of the active substance B.I.d.1.a.3 B.I.d.1.a.3 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - Extension of storage period of a biological/ immunological active substance not in accordance with an approved stability protocol

ALBUREX 20 SOLUTION FOR INFUSION 200G/L	1372/22T	20630	CSL BEHRING GMBH	B.I.d.1.b.3 B.I.d.1.b.3 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Storage conditions - Change in storage conditions of the active substance B.I.d.1.a.3 B.I.d.1.a.3 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - Extension of storage period of a biological/ immunological active substance not in accordance with an approved stability protocol
DASATINIB/TEVA TABLET, FILM COATED 20MG	6747/22T	023459	TEVA BV	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
DASATINIB/TEVA TABLET, FILM COATED 100MG	6744/22T	023462	TEVA BV	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
DASATINIB/TEVA TABLET, FILM COATED 70MG	6745/22T	023461	TEVA BV	B.I.z B.I.z - QUALITY

				CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
DASATINIB/TEVA TABLET, FILM COATED 50MG	6746/22T	023460	TEVA BV	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
MIRTAZAPINE AUROBINDO TABLET, ORODISPERSIBLE 15MG	6229/22T	020437	AUROBINDO PHARMA (MALTA) LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
MIRTAZAPINE AUROBINDO TABLET, ORODISPERSIBLE 30MG	6228/22T	020438	AUROBINDO PHARMA (MALTA) LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
MIRTAZAPINE AUROBINDO TABLET, ORODISPERSIBLE 45MG	6227/22T	020439	AUROBINDO PHARMA (MALTA) LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release

TICOVAC JUNIOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.25ML/DOSE	6773/22T, 6774/22T, 6775/22T	023267	PFIZER HELLAS AE	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes B.I.z B.I.z - Quality change - Active substance - Other variation B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
TICOVAC SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.5ML/DOSE	6770/22T, 6771/22T, 6772/22T	023266	PFIZER HELLAS AE	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes B.I.z B.I.z - Quality change - Active substance - Other variation B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing

				process of the active substance - Minor change in the manufacturing process of the active substance
MENTIFAR TABLET, FILM COATED 10MG	5804/22T, 5805/22T, 5806/22T	022204	RAFARM S.A.	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.a.2.a B.II.a.2.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change in the shape or dimensions of the pharmaceutical form - Immediate release tablets, capsules, suppositories and pessaries
MENTIFAR TABLET, FILM COATED 20MG	5801/22T, 5802/22T, 5803/22T	022205	RAFARM S.A.	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.a.2.a B.II.a.2.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change in the shape or dimensions of the pharmaceutical form - Immediate release tablets, capsules, suppositories and pessaries
CINACALCET/PHARMAZAC TABLET, FILM COATED 90MG	2422/22T	023018	PHARMAZAC S.A.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or

				change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
CINACALCET/PHARMAZAC TABLET, FILM COATED 60MG	2421/22T	023017	PHARMAZAC S.A.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
CINACALCET/PHARMAZAC TABLET, FILM COATED 30MG	2420/22T	023016	PHARMAZAC S.A.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active

				substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
TAKS SOLUTION FOR INJECTION OR INFUSION 75MG/3ML	8132/22T, 8133/22T	019824	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
CANDESARTAN KRKA TABLET 16MG	5631/22T	021503	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDESARTAN KRKA TABLET 4MG	5633/22T	021501	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

CANDESARTAN KRKA TABLET 8MG	5632/22T	021502	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDESARTAN KRKA TABLET 32MG	5630/22T	021504	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLAMATAN TABLET, FILM COATED 12.5MG	8138/22T, 8139/22T	022952	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
EZIPOL GASTRO-RESISTANT CAPSULE, HARD 20MG	3288/22T, 3289/22T, 3290/22T	018597	KLEVA PHARMACEUTICALS S.A. (TRADING AS KLEVA S.A.)	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.a.3.b.5 B.II.a.3.b.5 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that is supported by a bioequivalence study
RENNIE DOUBLE ACTION TABLET, CHEWABLE 625MG/73.5MG/150MG	6776/22T	023471	BAYER HELLAS ABEE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CARAMLO TABLET 10MG/16MG	6849/22T	022064	ZENTIVA K.S.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
CARAMLO TABLET 5MG/8MG	6848/22T	022063	ZENTIVA K.S.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
LENALIDOMIDE NORAMEDA CAPSULE, HARD 25MG	6641/22T, 6642/22T	023663	UAB NORAMEDA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LENALIDOMIDE NORAMEDA CAPSULE, HARD 10MG	6645/22T, 6646/22T	023661	UAB NORAMEDA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LENALIDOMIDE NORAMEDA CAPSULE, HARD 15MG	6643/22T, 6644/22T	023662	UAB NORAMEDA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally

				Authorised Products
LENALIDOMIDE NORAMEDA CAPSULE, HARD 5MG	6647/22T, 6648/22T	023660	UAB NORAMEDA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
NIMM TABLET 100MG	7928/22T	017715	CODAL-SYNTO LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Other variation
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/160MG/25MG	2905/22T	023350	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/320MG/25MG	2906/22T	023351	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM	2904/22T	023349	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

COATED 5MG/160MG/12.5MG				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SEROXAT TABLET, FILM COATED 20MG	7137/21T	014178	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
COSYREL TABLET, FILM COATED 5MG/10MG	6368/22T	022634	LES LABORATOIRES SERVIER	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
COSYREL TABLET, FILM COATED 10MG/5MG	6369/22T	022635	LES LABORATOIRES SERVIER	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
COSYREL TABLET, FILM COATED 10MG/10MG	6370/22T	022636	LES LABORATOIRES SERVIER	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
COSYREL TABLET, FILM COATED 5MG/5MG	6367/22T	022633	LES LABORATOIRES SERVIER	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PALEXIA RETARD TABLET, PROLONGED-RELEASE 50MG	5657/22T, 5658/22T	021256	GRUNENTHAL GMBH	B.II.a.3.b.6 B.II.a.3.b.6 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level

				B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes
PALEXIA RETARD TABLET, PROLONGED-RELEASE 100MG	5655/22T, 5656/22T	021257	GRUNENTHAL GMBH	B.II.a.3.b.6 B.II.a.3.b.6 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes
RAPIBLOC POWDER FOR SOLUTION FOR INFUSION 300MG/VIAL	5094/22T, 5095/22T, 5096/22T, 5097/22T, 5098/22T	022744	AMOMED PHARMA GMBH.	B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finishe B.II.b.4.d B.II.b.4.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch

				size ranges) of the finished product - The change relates to all other pharmaceutic B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC li B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finishe
SOOLANTRA CREAM 10MG/G	7243/22T	022320	GALDERMA INTERNATIONAL,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SOOLANTRA CREAM 10MG/G	7382/22T	022320	GALDERMA INTERNATIONAL,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	6878/22T	022345	BIOTEST PHARMA GMBH	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval

				change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product
OPTODROP-CO EYE DROPS, SOLUTION (2+0.5)%	8376/22T	020546	RAFARM S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALBUNORM 5% SOLUTION FOR INFUSION 50G/L	4259/22T	020670	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
ALBUNORM 4% SOLUTION FOR INFUSION 40G/L	4258/22T	020919	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the

				active substance - Minor change in the manufacturing process of the active substance
ALBUNORM 20% SOLUTION FOR INFUSION 200G/L	4257/22T	020671	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
ALBUNORM 25% SOLUTION FOR INFUSION 250G/L	4260/22T	020920	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
OPTODROP EYE DROPS, SOLUTION 2% W/V	8375/22T	020512	RAFARM S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	3866/22T	023151	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	3865/22T	023150	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	3864/22T	023149	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	3863/22T	023148	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	3317/22T	023151	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	3314/22T	023148	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	3316/22T	023150	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	3315/22T	023149	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ALBUNORM 4% SOLUTION FOR INFUSION 40G/L	1379/22T, 1380/22T, 1381/22T	020919	OCTAPHARMA (IP) SPRL	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES -

				FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUNORM 25% SOLUTION FOR INFUSION 250G/L	1388/22T, 1389/22T, 1390/22T	020920	OCTAPHARMA (IP) SPRL	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step

				procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUNORM 20% SOLUTION FOR INFUSION 200G/L	1385/22T, 1386/22T, 1387/22T	020671	OCTAPHARMA (IP) SPRL	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUNORM 5% SOLUTION FOR INFUSION 50G/L	1382/22T, 1383/22T, 1384/22T	020670	OCTAPHARMA (IP) SPRL	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other

				regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 1MG/ML	7602/22T	023490	B. BRAUN MELSUNGEN AG	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 5MG/ML	7601/22T	023491	B. BRAUN MELSUNGEN AG	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OMNIC MODIFIED-RELEASE CAPSULE, HARD 0.4MG	7568/22T	022169	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OMNIC TOCAS TABLET, PROLONGED-RELEASE 0.4MG	7569/22T	022184	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AZYTER EYE DROPS, SOLUTION 15MG/G	4972/21T	021320	LABORATOIRES THEA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
AUGMENTIN POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	9560/21T	019702	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
AUGMENTIN TABLET, FILM COATED 500MG/125MG	9561/21T	012656	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
AUGMENTIN TABLET, FILM COATED 1G	9562/21T	019515	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CANDESARTAN TAD TABLET 16MG	3677/22T, 3678/22T, 3679/22T, 3680/22T	020827	TAD PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
CANDESARTAN TAD TABLET 32MG	3681/22T, 3682/22T, 3683/22T, 3684/22T	020828	TAD PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing

				process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
QUELORAN TABLET, PROLONGED-RELEASE 200MG	5867/22T, 5868/22T, 5869/22T	023409	PHARMATHEN S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an

				already approved manufacturer
QUELORAN TABLET, PROLONGED-RELEASE 50MG	5873/22T, 5874/22T, 5875/22T	023407	PHARMATHEN S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
QUELORAN TABLET, PROLONGED-RELEASE 400MG	5861/22T, 5862/22T, 5863/22T	023411	PHARMATHEN S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
QUELORAN TABLET, PROLONGED-RELEASE 150MG	5870/22T, 5871/22T, 5872/22T	023408	PHARMATHEN S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance

				For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
QUELORAN TABLET, PROLONGED-RELEASE 300MG	5864/22T, 5865/22T, 5866/22T	023410	PHARMATHEN S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
BENDAMUSTINE ACCORD POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 2.5MG/ML	4993/22T	022411	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
IRINOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	1675/22T	022453	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FOSTER INHALATION SOLUTION, PRESSURISED 100/6 MCG/ACTUATION	6991/22T	020440	CHIESI FARMACEUTICI SPA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
FOSTER INHALATION SOLUTION, PRESSURISED (200MCG/6MCG)/ACTUATION	6992/22T	023294	CHIESI FARMACEUTICI SPA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
OTRIVIN NASAL SPRAY 0.1%	7608/21T, 7609/21T	017439	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
OTRIVIN NASAL DROPS 0.1%	7606/21T, 7607/21T	017436	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
OTRIVIN NASAL DROPS 0.05%	7604/21T, 7605/21T	017437	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
OTRIVIN PRESERVATIVE FREE NASAL SPRAY, SOLUTION 0.1% W/V	7602/21T, 7603/21T	022849	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer

				(replacement or addition)
PULMICORT NEBULISER SUSPENSION 0.25MG/ML	7206/22T	014265	ASTRAZENECA AB	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
PULMICORT NEBULISER SUSPENSION 0.5MG/ML	7205/22T	014266	ASTRAZENECA AB	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New

				certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
ALMIRAL SUPPOSITORY 100MG	7852/22T	011764	MEDOCHEMIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
ALMIRAL SUPPOSITORY 50MG	7853/22T	011763	MEDOCHEMIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under

				Articles 45 or 46 of Regulation 1901/2006 - Other variation
DEXATON ORAL SOLUTION 2MG/5ML	3368/21T, 3369/21T	021792	VIANEX S.A	C.I.6.a C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
IRINOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	9647/21T	022453	ACCORD HEALTHCARE S.L.U	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
CARAMLO TABLET 5MG/8MG	7373/22T	022063	ZENTIVA K.S.	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
CARAMLO TABLET 10MG/16MG	7374/22T	022064	ZENTIVA K.S.	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
FUROSEMIDE ACCORD SOLUTION FOR INJECTION OR INFUSION 10MG/ML	7019/22T	022517	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient

				(when mentioned in the dossier)*
ASPENDOS TABLET 100MG	6657/22T, 6658/22T	020929	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
SILDENAFIL MYLAN TABLET, FILM COATED 100MG	7937/22T	023105	MYLAN IRELAND LIMITED	A.z A.z - ADMINISTRATIVE

				CHANGES - Other variation
SILDENAFIL MYLAN TABLET, FILM COATED 25MG	7939/22T	023103	MYLAN IRELAND LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
EZETIMIBE/MYLAN TABLET 10MG	7940/22T	023155	MYLAN PHARMACEUTICALS LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
SILDENAFIL MYLAN TABLET, FILM COATED 50MG	7938/22T	023104	MYLAN IRELAND LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
REMEDIUM TABLET 5MG	6097/22T	007750	REMEDICA LTD	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
METHOTREXATE/PFIZER TABLET 2.5MG	8658/21T	002904	PFIZER HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
CUTIVATE CREAM 0.05%	6305/22T, 6306/22T	016799	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or

				quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CLOMENTIN TABLET, FILM COATED 5MG	8101/22T	021240	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CLOMENTIN TABLET, FILM COATED 20MG	8098/22T	021243	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CLOMENTIN TABLET, FILM COATED 15MG	8099/22T	021242	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CLOMENTIN TABLET, FILM COATED 10MG	8100/22T	021241	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VIVIDRIN EYE DROPS 2%	8227/22T	011977	DR.GERHARD MANN CHEM.-PHARM. FABRIK GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
IMATINIB TAD TABLET, FILM COATED 100MG	7306/22T	023685	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
IMATINIB TAD TABLET, FILM COATED 400MG	7305/22T	023684	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP

				changes (e.g. agreed wording + template change)
OLMESARTAN TAD TABLET, FILM COATED 40MG	2576/22T	022823	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
OLMESARTAN TAD TABLET, FILM COATED 20MG	2575/22T	022822	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority + QRD update
OLMESARTAN TAD TABLET, FILM COATED 10MG	2574/22T	022821	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
AZYTER EYE DROPS, SOLUTION 15MG/G	8605/21T, 8606/21T, 8607/21T	021320	LABORATOIRES THEA	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or

				addition of a site where batch control/testing takes place
FINASTERIDE ACCORD TABLET, FILM COATED 1MG	10400/20T	020815	ACCORD HEALTHCARE S.L.U	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FINASTERIDE ACCORD TABLET, FILM COATED 1MG	10400/20T	020815	ACCORD HEALTHCARE S.L.U	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FINASTERIDE ACCORD TABLET, FILM COATED 5MG	10401/20T	020816	ACCORD HEALTHCARE S.L.U	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FINASTERIDE ACCORD TABLET, FILM COATED 5MG	10401/20T	020816	ACCORD HEALTHCARE S.L.U	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
NUROFEN FOR CHILDREN 4% STRAWBERRY ORAL SUSPENSION 4%	4970/22T	021713	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NUROFEN FOR CHILDREN 4% ORANGE ORAL SUSPENSION 4%	4971/22T	021712	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COVERSYL TABLET, FILM COATED 10MG	2993/22T	020031	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
PRETERAX TABLET, FILM COATED 5MG/1.25MG	2995/22T	020257	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COVERAM TABLET 5MG/5MG	2987/22T	020465	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COVERAM TABLET 5MG/10MG	2988/22T	020466	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COVERAM TABLET 10MG/5MG	2989/22T	020467	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
PRETERAX TABLET, FILM COATED 10MG/2.5MG	2986/22T	20661	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COVERSYL PLUS ARGININE TABLET, FILM COATED 2.5MG/0.625MG	2994/22T	020256	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VIACORAM TABLET 3.5MG/2.5MG	2980/22T	022642	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer

				(replacement or addition)
TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/10MG	2977/22T	022157	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/5MG	2978/22T	022158	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TRIVERAM TABLET, FILM COATED 20MG/5MG/5MG	2997/22T	022773	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TRIVERAM TABLET, FILM COATED 20MG/10MG/5MG	2998/22T	022774	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VIACORAM TABLET 7MG/5MG	2981/22T	022643	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COSYREL TABLET, FILM COATED 5MG/10MG	2983/22T	022634	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TRIVERAM TABLET, FILM COATED 40MG/10MG/10MG	3000/22T	022776	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COSYREL TABLET, FILM COATED 10MG/5MG	2984/22T	022635	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COSYREL TABLET, FILM COATED 10MG/10MG	2985/22T	022636	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TRIVERAM TABLET, FILM COATED 20MG/10MG/10MG	2999/22T	022775	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COSYREL TABLET, FILM COATED 5MG/5MG	2982/22T	022633	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a

				new manufacturer (replacement or addition)
TRIVERAM TABLET, FILM COATED 10MG/5MG/5MG	2996/22T	022772	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/5MG	2976/22T	022156	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COVERAM TABLET 10MG/10MG	2990/22T	020468	LES LABORATOI	B.III.1.a.3 B.III.1.a.3 - QUALITY

			RES SERVIER	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/10MG	2979/22T	022159	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COVERSYL TABLET, FILM COATED 2.5MG	2991/22T	020029	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COVERSYL TABLET, FILM COATED 5MG	2992/22T	020030	LES LABORATOIRES SERVIER	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
KANILAD TABLET, FILM COATED 150MG	5000/22T	022715	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
KANILAD TABLET, FILM COATED 50MG	5002/22T	022713	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
KANILAD TABLET, FILM COATED 200MG	4999/22T	022716	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which

				no new additional data is required to be submitted by the MAH
KANILAD TABLET, FILM COATED 100MG	5001/22T	022714	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LOBIVON PLUS TABLET, FILM COATED 5MG/25MG	4613/22T	021789	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.c.1.z B.II.c.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Other changes
LOBIVON PLUS TABLET, FILM COATED 5MG/12.5MG	4614/22T	021788	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.c.1.z B.II.c.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Other changes
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	5191/22T	022396	SANOFI PASTEUR.	B.IV.z B.IV.z - QUALITY CHANGES - Medical Devices - Other variation
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	1973/22T, 1974/22T, 4642/22T	023308	OCTAPHARMA (IP) SPRL	B.II.b.3.b B.II.b.3.b - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process of a sterile finished product after the primary packaging step B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
VIZITRAV EYE DROPS, SOLUTION 40MCG/ML	9206/21T	023221	BAUSCH + LOMB IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP

				changes (e.g. agreed wording + template change)
CLARISCAN SOLUTION FOR INJECTION 0.5MMOL/ML	4265/22T	022730	GE HEALTHCARE AS	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	4506/22T	023308	OCTAPHARMA (IP) SPRL	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
DEFERASIROX PHARMASCIENCE TABLET, FILM COATED 90MG	2740/22T, 2741/22T, 2742/22T, 2743/22T	023523	PHARMASCIENCE INTERNATIONAL LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the

				manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
DEFERASIROX PHARMASCIENCE TABLET, FILM COATED 360MG	2748/22T, 2749/22T, 2750/22T, 2751/22T	023525	PHARMASCIENCE INTERNATIONAL LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
DEFERASIROX PHARMASCIENCE TABLET, FILM COATED 180MG	2744/22T, 2745/22T, 2746/22T, 2747/22T	023524	PHARMASCIENCE INTERNATIONAL LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.a.1.z B.I.a.1.z -

				QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	3825/22T, 3826/22T, 3827/22T	023688	TEVA PHARMA BV	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
EBRILON TABLET, FILM COATED 5MG	8156/22T	21965	MEDOCHE MIE LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
AFITEN TABLET 5MG	8210/21T	020286	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosi

				milar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
AFITEN TABLET 10MG	8209/21T	020287	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RIDOCA CAPSULE, HARD 180MG	7442/22T, 7443/22T, 7444/22T, 7445/22T, 7446/22T, 7447/22T, 7448/22T, 7449/22T, 7450/22T	022134	AENORASIS SA	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
RIDOCA CAPSULE, HARD 5MG	7478/22T, 7479/22T, 7480/22T, 7481/22T, 7482/22T, 7483/22T, 7484/22T, 7485/22T, 7486/22T	022130	AENORASIS SA	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
RIDOCA CAPSULE, HARD 20MG	7469/22T, 7470/22T, 7471/22T, 7472/22T, 7473/22T, 7474/22T, 7475/22T, 7476/22T, 7477/22T	022131	AENORASIS SA	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
RIDOCA CAPSULE, HARD 140MG	7451/22T, 7452/22T, 7453/22T, 7454/22T, 7455/22T, 7456/22T, 7457/22T, 7458/22T, 7459/22T	022133	AENORASIS SA	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
RIDOCA CAPSULE, HARD 250MG	7433/22T, 7434/22T, 7435/22T, 7436/22T, 7437/22T, 7438/22T, 7439/22T, 7440/22T, 7441/22T	022135	AENORASIS SA	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the

				immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
RIDOCA CAPSULE, HARD 100MG	7460/22T, 7461/22T, 7462/22T, 7463/22T, 7464/22T, 7465/22T, 7466/22T, 7467/22T, 7468/22T	022132	AENORASIS SA	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
KIVALA TABLET, FILM COATED	7286/22T, 7287/22T, 7288/22T, 7289/22T	022346	REMEDICA LTD	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes B.I.a.3.a B.I.a.3.a - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compare A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use
TRACHILID LOZENGE 8MG	6966/22T, 6967/22T	020315	ENGELHARD ARZNEIMITTEL GMBH & CO. KG	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.a B.II.e.7.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Change in the name of a supplier of a packaging component. If the information is not needed in the dossier CMDh recommends

				deletion of this information.
TENOVIRAL TABLET, FILM COATED 245MG	7217/22T, 7218/22T	022351	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
TENOVIRAL TABLET, FILM COATED 163MG	7221/22T, 7222/22T	022349	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
TENOVIRAL TABLET, FILM COATED 123MG	7223/22T, 7224/22T	022348	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of

				the finished product - As packaged for sale (supported by real time data) B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
TENOVIRAL TABLET, FILM COATED 204MG	7219/22T, 7220/22T	022350	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
MIVIENT INHALATION POWDER, HARD CAPSULE 10MCG	6937/21T	null	TEVA BV	B.I.c.1.a B.I.c.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in immediate packaging of the active substance - Qualitative and/or quantitative composition
CONCERTA TABLET, PROLONGED-RELEASE 36MG	5425/22T	020340	JANSSEN-CILAG INTERNATIONAL NV	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which

				the manufacturer/importer is responsible do not include batch release
CONCERTA TABLET, PROLONGED-RELEASE 18MG	5426/22T	020339	JANSSEN-CILAG INTERNATIONAL NV	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
CONCERTA TABLET, PROLONGED-RELEASE 54MG	5424/22T	020336	JANSSEN-CILAG INTERNATIONAL NV	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
DICLODUO COMBI MODIFIED-RELEASE CAPSULE, HARD	5443/22T, 5444/22T, 5445/22T, 5446/22T, 5447/22T, 5448/22T, 5449/22T, 5450/22T, 5451/22T, 5452/22T	022360	PHARMASWISS CESKA REPUBLIKA SRO	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
ACTONEL (2 CONSEQUENTIAL DAYS PER MONTH) TABLET, FILM COATED 75MG	5462/22T	020392	INNOVIS PHARMA S.A.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ACTONEL OAW TABLET, FILM COATED 35MG	5461/22T	019723	INNOVIS PHARMA S.A.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 40MG	4989/22T	021781	TAD PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 20MG	4990/22T	021780	TAD PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	7274/22T, 7275/22T, 7276/22T	020187	TEVA GMBH	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	7271/22T, 7272/22T, 7273/22T	022376	TEVA GMBH	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or

				addition) for the active substance or a starting material/intermediate B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
MELOREM TABLET 7.5MG	7409/22T	020288	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
MELOREM TABLET 15MG	7410/22T	020289	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
MAGRILAN CAPSULE, HARD 20MG	3941/22T, 6473/22T, 6474/22T, 6475/22T, 6476/22T, 6477/22T	019891	MEDOCHE MIE LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate

				from an already approved manufacturer
VESICARE TABLET, FILM COATED 5MG	8739/21T	019727	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
VESICARE ORAL SUSPENSION 1MG/ML	8737/21T	022366	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
VESICARE TABLET, FILM COATED 10MG	8738/21T	019751	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/25MG	9667/21T	022573	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/25MG	9669/21T	022575	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment,

				e.g. translations are not yet agreed upon
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/12.5MG	9668/21T	022574	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/12.5MG	9666/21T	022572	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of

				Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/25MG	2571/22T	022573	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/25MG	2573/22T	022575	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/12.5MG	2572/22T	022574	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/12.5MG	2570/22T	022572	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
MIFEGYNE TABLET 200MG	7932/21T	022983	EXELGYN	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
DACARBAZIN LIPOMED POWDER FOR SOLUTION FOR INJECTION/INFUSION 200MG/VIAL	5482/22T	021811	LIPOMED GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient -

				European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DACARBAZIN LIPOMED POWDER FOR SOLUTION FOR INJECTION/INFUSION 200MG/VIAL	5483/22T	021811	LIPOMED GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DACARBAZIN LIPOMED POWDER FOR SOLUTION FOR INJECTION/INFUSION 200MG/VIAL	5481/22T	021811	LIPOMED GMBH	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
FERINJECT SOLUTION FOR INJECTION OR INFUSION 50MG IRON/ML	4006/21T	020795	VIFOR FRANCE	B.II.b.1.c B.II.b.1.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the

				manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes
INTRATECT SOLUTION FOR INFUSION 100G/L	6753/22T	022263	BIOTEST PHARMA GMBH	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/320MG/25MG	3053/22T	023351	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the

				assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 5MG/160MG/12.5MG	3054/22T	023349	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/160MG/25MG	3052/22T	023350	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent

				authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	5877/22T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product
GYNO-CANESTEN VAGINAL CAPSULE, SOFT 500MG	4281/22T, 4282/22T, 4283/22T, 4284/22T	023280	BAYER HELLAS ABEE	B.II.c.1.g B.II.c.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Where there is no monograph in the European Pharmacopoeia or the national pharmacopoeia of a Member State for the excipient, a change in specification from in-house to a non-official Pharmacopoeia or a Pharmacopoeia of a third country
GYNO-CANESTEN VAGINAL CAPSULE, SOFT 500MG	4280/22T	023280	BAYER HELLAS ABEE	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing

				process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place
LEXILIUM TABLET 3MG	7404/22T, 7405/22T, 7406/22T, 7407/22T	009936	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State -

				Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. E B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the
ROXITAN CAPSULE, HARD 20MG	7829/22T	012110	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
CAPOLEV PLUS TABLET 16/12.5MG	7653/22T	021611	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing

				authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
CAPOLEV PLUS TABLET 8/12.5MG	7654/22T	021610	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
CAPOLEV PLUS TABLET 32/25MG	7651/22T	021613	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
CAPOLEV PLUS TABLET 32/12.5MG	7652/22T	021612	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by

				the competent authority
FIXAPROST EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (50MCG/5MG)/ML	4985/22T	023359	LABORATOIRES THEA	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
CAPOLEV TABLET 32MG	7639/22T	021536	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
CAPOLEV TABLET 4MG	7642/22T	021533	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
CAPOLEV TABLET 16MG	7640/22T	021535	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
CAPOLEV TABLET 8MG	7641/22T	021534	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
HEXAFLU DAY & NIGHT TABLET 500MG/60MG AND 500MG/25MG	7945/20T	023165	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.11 z) Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan Other variation
GAVISCON DOUBLE ACTION LIQUID ORAL SUSPENSION	2059/22T, 2060/22T	022026	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TAVANIC TABLET, FILM COATED 500MG	6265/22T, 6266/22T	019283	SANOFI-AVENTIS GROUPE	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
SEROQUEL XR TABLET, PROLONGED-RELEASE 50MG	4042/22T, 4043/22T, 4044/22T, 4045/22T, 4046/22T, 4047/22T, 4048/22T, 4049/22T, 4050/22T	020356	ASTRAZENECA AB	B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.2.a B.II.b.2.a

				- QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active s B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/re
SEROQUEL XR TABLET, PROLONGED-RELEASE 200MG	4078/22T, 4079/22T, 4080/22T, 4081/22T, 4082/22T, 4083/22T, 4084/22T, 4085/22T, 4086/22T	020357	ASTRAZENECA AB	B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a

				- QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active s B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/re

SEROQUEL XR TABLET, PROLONGED-RELEASE 300MG	4069/22T, 4070/22T, 4071/22T, 4072/22T, 4073/22T, 4074/22T, 4075/22T, 4076/22T, 4077/22T	020358	ASTRAZENECA AB	B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the

				active s B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/re
SEROQUEL XR TABLET, PROLONGED-RELEASE 400MG	4060/22T, 4061/22T, 4062/22T, 4063/22T, 4064/22T, 4065/22T, 4066/22T, 4067/22T, 4068/22T	020359	ASTRAZENECA AB	B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or

				finished product, B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active s B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/re
SEROQUEL XR TABLET, PROLONGED-RELEASE 150MG	4051/22T, 4052/22T, 4053/22T, 4054/22T, 4055/22T, 4056/22T, 4057/22T, 4058/22T, 4059/22T	020699	ASTRAZENECA AB	B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer,

				batch release arrangements A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active s B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/re
SEROQUEL TABLET, FILM COATED 25MG	4087/22T, 4088/22T, 4089/22T, 4090/22T, 4091/22T, 4092/22T, 4093/22T, 4094/22T, 4095/22T	017716	ASTRAZENECA AB	B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer,

				batch release arrangements B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active s B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/re
SEROQUEL TABLET, FILM COATED 100MG	4096/22T, 4097/22T, 4098/22T, 4099/22T, 4100/22T, 4101/22T, 4102/22T, 4103/22T, 4104/22T	017717	ASTRAZENECA AB	B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer,

				batch release arrangements and B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active s B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/re
SEROQUEL TABLET, FILM COATED 200MG	4105/22T, 4106/22T, 4107/22T, 4108/22T, 4109/22T, 4110/22T, 4111/22T, 4112/22T, 4113/22T	017718	ASTRAZENECA AB	B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or

				addition of a manufacturing site fo B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active s B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/re
SMOFLIPID EMULSION FOR INFUSION 20%	4595/22T, 4596/22T, 4597/22T, 4598/22T, 4599/22T	020184	FRESENIUS KABI HELLAS AE	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change

				in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
AZACITIDINE PHARMASCIENCE POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	5003/22T	023641	PHARMASCIENCE INTERNATIONAL LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
FLUNOL CAPSULE, HARD 100MG	7632/22T	021602	PHARMA Q S.A.	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
FLUVASTATIN ACCORD TABLET, PROLONGED-RELEASE 80MG	6735/22T, 6736/22T, 6737/22T	021563	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site
IVIVERZ TABLET, FILM COATED 600MG/300MG	6766/22T, 6767/22T, 6768/22T, 6769/22T	022685	ACCORD HEALTHCARE S.L.U	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compare B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th
HOLESTATIN TABLET, FILM COATED 10MG	6577/22T	022677	DEMO S.A.	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
HOLESTATIN TABLET, FILM COATED 40MG	6575/22T	022679	DEMO S.A.	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
HOLESTATIN TABLET, FILM COATED 20MG	6576/22T	022678	DEMO S.A.	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
HOLESTATIN TABLET, FILM COATED 5MG	6578/22T	022676	DEMO S.A.	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the

				active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
ODELO TABLET, FILM COATED 2.5MG	2667/22T, 2668/22T, 2669/22T, 2670/22T, 2671/22T	023595	ELPEN PHARMACEUTICAL CO INC	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition A.7 A.7 -

				ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat
ODELO TABLET, FILM COATED 20MG	2682/22T, 2683/22T, 2684/22T, 2685/22T, 2686/22T	023598	ELPEN PHARMACEUTICAL CO INC	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product -

				Replacement or addition A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat
ODELO TABLET, FILM COATED 10MG	2672/22T, 2673/22T, 2674/22T, 2675/22T, 2676/22T	023596	ELPEN PHARMACEUTICAL CO INC	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and

				quality control testing of the finished product - Replacement or addition A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat
ODELO TABLET, FILM COATED 15MG	2677/22T, 2678/22T, 2679/22T, 2680/22T, 2681/22T	023597	ELPEN PHARMACEUTICAL CO INC	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat
BUSCOPAN SOLUTION FOR INJECTION 20MG/ML	2195/22T, 2196/22T	003121	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
ZALEPIN RAPID TABLET, ORODISPERSIBLE 15MG	7062/22T	022080	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ZALEPIN RAPID TABLET, ORODISPERSIBLE 20MG	7061/22T	022081	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ZALEPIN RAPID TABLET, ORODISPERSIBLE 10MG	7063/22T	022079	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer

				(replacement or addition)
ZALEPIN RAPID TABLET, ORODISPERSIBLE 5MG	7064/22T	022078	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
CANDEPRESS COMP TABLET 8MG/12.5MG	4922/22T	021738	SAPIENS PHARMACEUTICALS LTD	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
CANDEPRESS COMP TABLET 16MG/12.5MG	4921/22T	021739	SAPIENS PHARMACEUTICALS LTD	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition

				or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
CANDEPRESS TABLET 16MG	4924/22T	021723	SAPIENS PHARMACEUTICALS LTD	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
CANDEPRESS TABLET 32MG	4923/22T	021724	SAPIENS PHARMACEUTICALS LTD	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
CANDEPRESS TABLET 8MG	4925/22T	021722	SAPIENS PHARMACEUTICALS LTD	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished

				product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
CANDEPRESS TABLET 4MG	4926/22T	021721	SAPIENS PHARMACEUTICALS LTD	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
CRESTOR TABLET, FILM COATED 40MG	1291/20T	019624	ASTRAZENECA AB	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
CRESTOR TABLET, FILM COATED 20MG	1292/20T	019623	ASTRAZENECA AB	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
CRESTOR TABLET, FILM COATED 10MG	1293/20T	019622	ASTRAZENECA AB	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.

CRESTOR TABLET, FILM COATED 5MG	1294/20T	019728	ASTRAZENECA AB	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PRELYNCA CAPSULE, HARD 100MG	3097/22T	022468	PHARMATHEN S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PRELYNCA CAPSULE, HARD 200MG	3099/22T	022470	PHARMATHEN S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PRELYNCA CAPSULE, HARD 25MG	3094/22T	022465	PHARMATHEN S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PRELYNCA CAPSULE, HARD 150MG	3098/22T	022469	PHARMATHEN S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PRELYNCA CAPSULE, HARD 300MG	3101/22T	022472	PHARMATHEN S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of

				wording agreed by the competent authority that do not require any further assessment
PRELYNCA CAPSULE, HARD 225MG	3100/22T	022471	PHARMATHEN S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PRELYNCA CAPSULE, HARD 50MG	3095/22T	022466	PHARMATHEN S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PRELYNCA CAPSULE, HARD 75MG	3096/22T	022467	PHARMATHEN S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PRELYNCA CAPSULE, HARD 100MG	335/22T	022468	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PRELYNCA CAPSULE, HARD 200MG	332/22T	022470	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure

				concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PRELYNCA CAPSULE, HARD 25MG	329/22T	022465	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PRELYNCA CAPSULE, HARD 150MG	331/22T	022469	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the

				outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PRELYNCA CAPSULE, HARD 300MG	334/22T	022472	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PRELYNCA CAPSULE, HARD 225MG	333/22T	022471	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PRELYNCA CAPSULE, HARD 50MG	330/22T	022466	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PRELYNCA CAPSULE, HARD 75MG	336/22T	022467	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under

				Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TRINISTEM TABLET, FILM COATED 600MG/200MG/245MG	7596/22T, 7597/22T, 7598/22T, 7599/22T	022699	REMEDICA LTD	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
TANAFRA EYE DROPS, SOLUTION 50MCG/ML	6366/21T, 6367/21T	022906	PHARMATHEN S.A.	B.II.e.5.d B.II.e.5.d - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products B.II.f.1.b.2 B.II.f.1.b.2 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - After first opening (supported by real time data)
ENSTILAR CUTANEOUS FOAM (50MCG/0.5MG)/G	4043/21T	022545	LEO PHARMA A/S	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ONDANSETRON ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	1358/22T, 1359/22T	020718	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

				B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
EZETIMIBE/SIMVASTATIN ACCORD TABLET 10MG/10MG	6247/22T	023292	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
EZETIMIBE/SIMVASTATIN ACCORD TABLET 10MG/20MG	6246/22T	023293	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
BUSCOPAN SOLUTION FOR INJECTION 20MG/ML	2080/21T	003121	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Other variation
SOLIAN TABLET, FILM COATED 400MG	2083/21T	020095	SANOFI-AVENTIS GROUPE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CLAFORAN POWDER FOR SOLUTION FOR INJECTION 1G	2082/21T	008403	SANOFI-AVENTIS CYPRUS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BUSCOPAN PLUS TABLET, FILM COATED	2081/21T	014583	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
STILNOX TABLET, FILM COATED 10MG	2079/21T	019612	SANOFI-AVENTIS GROUPE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SOLIAN TABLET, FILM COATED 400MG	8954/20T	020095	SANOFI-AVENTIS GROUPE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
EXATRON TABLET, FILM COATED	7528/22T, 7529/22T, 7530/22T, 7531/22T, 7532/22T	022347	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate /

				reagent used in the manufacturing process of the B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where r B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	6968/22T	023144	ACCORD HEALTHCARE S.L.U	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size

ATORVASTATIN AUROBINDO TABLET, FILM COATED 20MG	3167/22T	022701	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ATORVASTATIN AUROBINDO TABLET, FILM COATED 40MG	3168/22T	022702	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ATORVASTATIN AUROBINDO TABLET, FILM COATED 10MG	3166/22T	022700	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
NUROFEN EXPRESS CAPSULE, SOFT 400MG	553/22T	021486	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VALGANCICLOVIR ACCORD TABLET, FILM COATED 450MG	3813/22T	022452	ACCORD HEALTHCARE S.L.U	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product -

				Up to 10-fold compared to the originally approved batch size
DINAPLEX CAPSULE, HARD 0.5MG/0.4MG	7002/22T, 7003/22T	023119	ELPEN PHARMACEUTICAL CO INC	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Updated certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

CONVERIDE TABLET, FILM COATED 150MG/12.5MG	4587/22T	022217	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIDE TABLET, FILM COATED 300MG/12.5MG	4586/22T	022218	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIDE TABLET, FILM COATED 300MG/25MG	4585/22T	022219	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
QUETIAPINE/GENERICS TABLET, FILM COATED 100MG	6684/22T	021522	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
QUETIAPINE/GENERICS TABLET, FILM COATED 25MG	6685/22T	021521	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
QUETIAPINE/GENERICS TABLET, FILM COATED 200MG	6683/22T	021523	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MONTOL TABLET, CHEWABLE 5MG	5902/22T, 5903/22T	021119	DELORBIS PHARMACEUTICALS LTD	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier -

				Re-test period/storage period - B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
MONTOL TABLET, CHEWABLE 4MG	5904/22T, 5905/22T	021118	DELORBIS PHARMACEUTICALS LTD	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
MONTOL TABLET, FILM COATED 10MG	5900/22T, 5901/22T	021120	DELORBIS PHARMACEUTICALS LTD	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)

CLINIMIX N14G30E SOLUTION FOR INFUSION	7142/22T	018591	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OXYCONTIN TABLET, PROLONGED-RELEASE 5MG	8055/22T	020346	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
OXYCONTIN TABLET, PROLONGED-RELEASE 80MG	8051/22T	018611	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place

OXYCONTIN TABLET, PROLONGED-RELEASE 20MG	8054/22T	018609	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
OXYCONTIN TABLET, PROLONGED-RELEASE 10MG	8053/22T	018608	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
OXYCONTIN TABLET, PROLONGED-RELEASE 40MG	8052/22T	018610	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
NANOGAM SOLUTION FOR INFUSION 100MG/ML	6255/22T	023227	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma

				Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	3348/22T	021235	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 150MG	3349/22T	022451	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 300MG	3347/22T	021234	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 200MG	3346/22T	021233	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	4380/22T, 4381/22T	021235	ACCORD HEALTHCARE S.L.U	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 150MG	4382/22T, 4383/22T	022451	ACCORD HEALTHCARE S.L.U	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of

				the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 300MG	4378/22T, 4379/22T	021234	ACCORD HEALTHCARE S.L.U	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance

				System Master File (PSMF) location
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 200MG	4376/22T, 4377/22T	021233	ACCORD HEALTHCARE S.L.U	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
LONARID N SUPPOSITORY (400+20+50) MG	3426/21T	019679	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LONARID N TABLET (400+10+50) MG	3425/21T	019678	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SINGULAIR GRANULES FOR ORAL SUSPENSION 4MG	6955/22T	019676	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SINGULAIR TABLET, CHEWABLE 4MG	6956/22T	019291	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MODIODAL TABLET 100MG	7296/22T	018944	TEVA BV	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VOLULYTE SOLUTION FOR INFUSION 6%	3109/22T, 3110/22T, 3111/22T	20656	FRESENIUS KABI DEUTSCHLAND GMBH, GERMANY	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
VOLULYTE SOLUTION FOR INFUSION 6%	1694/22T, 1695/22T	20656	FRESENIUS KABI DEUTSCHLAND GMBH, GERMANY	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant

				assessment by the competent authority is required*
LEVOTHYROXINE ACCORD TABLET 50MCG	6160/22T	023139	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LEVOTHYROXINE ACCORD TABLET 100MCG	6159/22T	023140	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LEVOTHYROXINE ACCORD TABLET 25MCG	6161/22T	023138	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
HEXAFLU DAY & NIGHT TABLET 500MG/60MG AND 500MG/25MG	5952/22T	023165	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms
ZOLOFT TABLET, FILM COATED 100MG	1977/22T, 1978/22T, 1979/22T, 1980/22T, 1981/22T	014678	UPJOHN HELLAS LTD	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsol B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification

				parameters and/or limits of the finished product - Change in the specification parameters and/or limits of the finished product to B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its correspo
ZOLOFT TABLET, FILM COATED 50MG	1982/22T, 1983/22T, 1984/22T, 1985/22T, 1986/22T	014677	UPJOHN HELLAS LTD	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsol B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change in the specification parameters and/or limits of the finished product to

				B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its correspo
ZOLOFT TABLET, FILM COATED 100MG	2419/22T	014678	UPJOHN HELLAS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ZOLOFT TABLET, FILM COATED 50MG	2418/22T	014677	UPJOHN HELLAS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data
ELOQUINE TABLET 250MG	7004/22T, 7005/22T, 7006/22T, 7007/22T, 7008/22T, 7009/22T, 7010/22T, 7011/22T	014654	MEDOCHE MIE LTD	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
GEODON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 20MG/ML	8763/21T, 8764/21T, 8765/21T, 8766/21T, 8767/21T	019457	UPJOHN HELLAS LTD	B.II.e.1.b.2 B.II.e.1.b.2 - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/ immunological medicinal products B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Deletion of one manufacturing process of the drug product manufacturing processes B.II.e.7.a B.II.e.7.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier
ERELAN TABLET, FILM COATED 400MG	4310/22T	022911	MEDOCHE MIE LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY

				CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
VILDAGLIPTIN PHARMATHEN TABLET 50MG	4870/22T	023063	PHARMATHEN S.A.	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
RAFAZIL ORAL SOLUTION 1MG/1ML	3839/22T, 3840/22T	022007	RAFARM S.A.	B.I.c.1.a B.I.c.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in immediate packaging of the active substance - Qualitative and/or quantitative composition B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
LEVOXACIN SOLUTION FOR INFUSION 5MG/ML	3051/22T	020749	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
BENYLIN CHILDREN'S NIGHT COUGH SYRUP (7MG/0.55MG)/5ML	6944/22T, 6945/22T, 6946/22T	009072	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
INDYLON CAPSULE, HARD 25MG	7880/22T	019972	MEDOCHEMIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
INDOXYL GEL 10MG/G+50MG/G	6261/22T, 6262/22T	019638	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the

				manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TORVACARD TABLET, FILM COATED 40MG	902/22T	020932	ZENTIVA K.S.	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
TORVACARD TABLET, FILM COATED 10MG	904/22T	020930	ZENTIVA K.S.	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
TORVACARD TABLET, FILM COATED 20MG	903/22T	020931	ZENTIVA K.S.	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active

				substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
TORVACARD TABLET, FILM COATED 80MG	901/22T	020933	ZENTIVA K.S.	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
BUVERA PATCH, TRANSDERMAL 52.5MCG/h	2595/22T	022608	RAFARM S.A.	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
BUVERA PATCH, TRANSDERMAL 70MCG/h	2596/22T	022609	RAFARM S.A.	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
BUVERA PATCH, TRANSDERMAL 35MCG/h	2594/22T	022607	RAFARM S.A.	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 40MG	3219/22T	023225	AUROBINDO PHARMA (MALTA) LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
VOLULYTE SOLUTION FOR INFUSION 6%	6106/21T, 6107/21T	20656	FRESENIUS KABI DEUTSCHLAND GMBH, GERMANY	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
FINGOLIMOD PHARMASCIENCE CAPSULE, HARD 0.5MG	5319/22T, 5320/22T	023482	PHARMASCIENCE INTERNATIONAL LTD	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test

				B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 40MG	299/22T	023225	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 5MG	296/22T	023222	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure

				concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 10MG	297/22T	023223	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 20MG	298/22T	023224	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the

				outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
EXTRANEAL SOLUTION FOR PERITONEAL DIALYSIS	6287/21T	023288	BAXTER (HELLAS) EPE	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
RENNIE DOUBLE ACTION TABLET, CHEWABLE 625MG/73.5MG/150MG	5291/21T	023471	BAYER HELLAS ABEE	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
DROLL EAR DROPS SOLUTION 1MG	2392/22T, 2393/22T	023352	GALENICA SA	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished

				product - Change outside the approved specifications limits range B.II.d.1.i B.II.d.1.i - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Ph. Eur. 2.9.40 Uniformity of dosage units is introduced to replace the currently registered method, either Ph. Eur. 2.9.5 (Uniformity of mass). or Ph. Eur. 2.9.6 (Uniformity of content)
CINACALCET/PHARMAZAC TABLET, FILM COATED 90MG	1989/22T	023018	PHARMAZAC S.A.	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place
CINACALCET/PHARMAZAC TABLET, FILM COATED 60MG	1988/22T	023017	PHARMAZAC S.A.	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place
CINACALCET/PHARMAZAC TABLET, FILM COATED 30MG	1987/22T	023016	PHARMAZAC S.A.	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place

BLISSEL VAGINAL GEL 50MCG/G	3860/22T	023538	ITF HELLAS A.E.	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
GRAFALON CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	7512/22T	017186	NEOVII BIOTECH GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
MUCOCOLD TABLET, FILM COATED 200MG/30MG	4256/21T, 4257/21T, 4258/21T	021691	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
MEDOVYNE POWDER FOR SOLUTION FOR INFUSION 250MG	6849/21T	023307	MEDOCHEMIE LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the

				originally approved batch size
PALIPERIDON TAD TABLET, PROLONGED-RELEASE 3MG	2920/22T	023013	TAD PHARMA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PALIPERIDON TAD TABLET, PROLONGED-RELEASE 9MG	2922/22T	023015	TAD PHARMA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PALIPERIDON TAD TABLET, PROLONGED-RELEASE 6MG	2921/22T	023014	TAD PHARMA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FLUDARA TABLET, FILM COATED 10MG	3197/20T	020545	GENZYME EUROPE B.V.	B.II.b.1 a) Secondary packaging site
FLUDARA POWDER FOR SOLUTION FOR INJECTION/INFUSION 50MG	3198/20T	018733	GENZYME EUROPE BV	B.II.b.1 a) Secondary packaging site

OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	2555/22T, 2556/22T, 2557/22T, 2558/22T, 2559/22T	021927	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product* B.II.d.2.e B.II.d.2.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur. B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
LOTEMAX EYE DROPS 0.5%	3556/22T	020230	DR.GERHARD MANN CHEM.-PHARM. FABRIK GMBH	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible

				do not include batch release
LOTEMAX EYE DROPS 0.5%	5847/22T	020230	DR.GERHARD MANN CHEM.-PHARM. FABRIK GMBH	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
NOSATEL SOLUTION FOR INJECTION OR INFUSION 50MG/2ML	5554/22T	020155	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LEVODOPA/CARBIDOPA/ENTACAPONE ACCORD TABLET, FILM COATED 200MG/50MG/200MG	6596/22T, 6597/22T, 6598/22T	022448	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site
LEVODOPA/CARBIDOPA/ENTACAPONE ACCORD TABLET, FILM COATED 150MG/37.5MG/200MG	6599/22T, 6600/22T, 6601/22T	022446	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site
LEVODOPA/CARBIDOPA/ENTACAPONE ACCORD TABLET, FILM COATED 100MG/25MG/200MG	6605/22T, 6606/22T, 6607/22T	022445	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or

				finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site
LEVODOPA/CARBIDOPA/ENTACAPONE ACCORD TABLET, FILM COATED 50MG/12.5MG/200MG	6611/22T, 6612/22T, 6613/22T	022449	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site
LEVODOPA/CARBIDOPA/ENTACAPONE ACCORD TABLET, FILM COATED 75MG/18.75MG/200MG	6608/22T, 6609/22T, 6610/22T	022450	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site

				for part or all of the manufacturing process of the finished product - Primary packaging site
LEVODOPA/CARBIDOPA/ENTACAPONE ACCORD TABLET, FILM COATED 125MG/31.25MG/200MG	6602/22T, 6603/22T, 6604/22T	022447	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site
CLINIMIX N14G30E SOLUTION FOR INFUSION	8628/20T	018591	BAXTER (HELLAS) EPE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
LENALIDOMIDE STADA CAPSULE, HARD 5MG	6728/22T	023619	STADA ARZNEIMITTEL AG	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
LENALIDOMIDE STADA CAPSULE, HARD 10MG	6727/22T	023621	STADA ARZNEIMITTEL AG	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
LENALIDOMIDE STADA CAPSULE, HARD 20MG	6725/22T	023623	STADA ARZNEIMITTEL AG	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
LENALIDOMIDE STADA CAPSULE, HARD 15MG	6726/22T	023622	STADA ARZNEIMITTEL AG	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
LENALIDOMIDE STADA CAPSULE, HARD 25MG	6724/22T	023624	STADA ARZNEIMITTEL AG	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch

				size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
SMOFKABIVEN EXTRA NITROGEN EMULSION FOR INFUSION	3966/22T, 3967/22T, 3968/22T, 3969/22T, 3970/22T, 3971/22T	023282	FRESENIUS KABI HELLAS A.E.	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermedia
SMOFKABIVEN EXTRA NITROGEN ELECTROLYTE FREE EMULSION FOR INFUSION	3960/22T, 3961/22T, 3962/22T, 3963/22T, 3964/22T, 3965/22T	023283	FRESENIUS KABI HELLAS A.E.	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermedia
LENALIDOMIDE STADA CAPSULE, HARD 5MG	6712/22T, 6713/22T, 6714/22T, 6715/22T	023619	STADA ARZNEIMITTEL AG	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place

LENALIDOMIDE STADA CAPSULE, HARD 2.5MG	6716/22T, 6717/22T, 6718/22T, 6719/22T	023618	STADA ARZNEIMITTEL AG	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
LENALIDOMIDE STADA CAPSULE, HARD 10MG	6704/22T, 6705/22T, 6706/22T, 6707/22T	023621	STADA ARZNEIMITTEL AG	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the

				name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
LENALIDOMIDE STADA CAPSULE, HARD 7.5MG	6708/22T, 6709/22T, 6710/22T, 6711/22T	023620	STADA ARZNEIMITTEL AG	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where

				relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
LENALIDOMIDE STADA CAPSULE, HARD 20MG	6696/22T, 6697/22T, 6698/22T, 6699/22T	023623	STADA ARZNEIMITTEL AG	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier

				of the active substance, starting material, reagent or intermediate use B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
LENALIDOMIDE STADA CAPSULE, HARD 15MG	6700/22T, 6701/22T, 6702/22T, 6703/22T	023622	STADA ARZNEIMITTEL AG	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use

				B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
LENALIDOMIDE STADA CAPSULE, HARD 25MG	6720/22T, 6721/22T, 6722/22T, 6723/22T	023624	STADA ARZNEIMITTEL AG	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/20MG	6758/22T	023127	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/40MG	6757/22T	023128	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
DONEPEZIL ACCORD TABLET, FILM COATED 5MG	6174/22T	021471	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of

				manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DONEPEZIL ACCORD TABLET, FILM COATED 10MG	6173/22T	021472	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LENALIDOMIDE STADA CAPSULE, HARD 5MG	3359/22T, 3360/22T	023619	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where

				relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LENALIDOMIDE STADA CAPSULE, HARD 2.5MG	3357/22T, 3358/22T	023618	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LENALIDOMIDE STADA CAPSULE, HARD 10MG	3363/22T, 3364/22T	023621	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

				test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LENALIDOMIDE STADA CAPSULE, HARD 7.5MG	3361/22T, 3362/22T	023620	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the

				manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LENALIDOMIDE STADA CAPSULE, HARD 20MG	3367/22T, 3368/22T	023623	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LENALIDOMIDE STADA CAPSULE, HARD 15MG	3365/22T, 3366/22T	023622	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT -

				Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LENALIDOMIDE STADA CAPSULE, HARD 25MG	3369/22T, 3370/22T	023624	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the

				active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
SUBUTEX TABLET, SUBLINGUAL 8MG	7065/22T, 7066/22T, 7067/22T	020073	INDIVIOR EUROPE LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure

SUBUTEX TABLET, SUBLINGUAL 0.4MG	7071/22T, 7072/22T, 7073/22T	020071	INDIVIOR EUROPE LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
SUBUTEX TABLET, SUBLINGUAL 2MG	7068/22T, 7069/22T, 7070/22T	020072	INDIVIOR EUROPE LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient

				(when mentioned in the dossier)* A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
GRABILEN CAPSULE, HARD 300MG	7920/22T	023040	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
GRABILEN CAPSULE, HARD 150MG	7921/22T	023039	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
GRABILEN CAPSULE, HARD 75MG	7922/22T	023038	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BETNOVATE CREAM 0.1% W/W	6307/22T, 6308/22T	016788	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include

				batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CERNEVIT POWDER FOR SOLUTION FOR INJECTION	7718/22T, 7719/22T, 7720/22T, 7721/22T	018769	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSUVADOR TABLET, FILM COATED 10MG	447/22T	022625	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal

				products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ROSUVADOR TABLET, FILM COATED 5MG	446/22T	022624	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ROSUVADOR TABLET, FILM COATED 20MG	448/22T	022626	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ROSUVADOR TABLET, FILM COATED 40MG	449/22T	022627	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

LACTULOSE RESOLUTION ORAL SOLUTION 3.3G/5ML	6614/22T, 6615/22T	020705	RELAX LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	2774/22T	020564	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	2774/22T	020564	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing

				authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RHOPHYLAC SOLUTION FOR INJECTION IN PREFILLED SYRINGES 300MCG/2ML	2770/22T	022756	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RHOPHYLAC SOLUTION FOR INJECTION IN PREFILLED SYRINGES 300MCG/2ML	2770/22T	022756	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a

				medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RHOPHYLAC SOLUTION FOR INJECTION IN PREFILLED SYRINGES 300MCG/2ML	2770/22T	022756	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RHOPHYLAC SOLUTION FOR INJECTION IN PREFILLED SYRINGES 300MCG/2ML	2770/22T	022756	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product

RHOPHYLAC SOLUTION FOR INJECTION IN PREFILLED SYRINGES 300MCG/2ML	2770/22T	022756	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	2772/22T	022790	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	2772/22T	022790	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new,

				updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	2772/22T	022790	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	2773/22T	022797	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File

				when changes do not affect the properties of the finished product
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	2773/22T	022797	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	2773/22T	022797	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUMEON SOLUTION FOR INFUSION 200G/l	2778/22T	022388	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other

				regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RIASTAP POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	2771/22T	021151	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RIASTAP POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	2771/22T	021151	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step

				procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RIASTAP POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	2771/22T	021151	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RIASTAP POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	2771/22T	021151	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	2777/22T	023121	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES -

				Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	2777/22T	023121	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	2775/22T	022321	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing

				authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	2775/22T	022321	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	2776/22T	023120	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product

BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	2776/22T	023120	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RHOPHYLAC SOLUTION FOR INJECTION IN PREFILLED SYRINGES 300MCG/2ML	2713/22T, 2714/22T	022756	CSL BEHRING GMBH	B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished

				product - Other changes
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	6844/22T	019744	SANOFI-AVENTIS GROUPE	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	6846/22T	019159	SANOFI-AVENTIS GROUPE	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	6845/22T	019160	SANOFI-AVENTIS GROUPE	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	6843/22T	019161	SANOFI-AVENTIS GROUPE	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
FINGOLIMOD PHARMATHEN CAPSULE, HARD 0.5MG	9663/21T	023228	PHARMATHEN S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
XYZAL TABLET, FILM COATED 5MG	3447/22T	020044	UCB PHARMA SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
XYZAL ORAL SOLUTION 0.5MG/ML	3448/22T	020127	UCB PHARMA SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
MYDRANE SOLUTION FOR INJECTION 0.2MG/ML+3.1MG/ML+10MG/ML	1363/22T	022523	LABORATOIRES THEA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LIDOCAINE ACCORD SOLUTION FOR INJECTION 20MG/ML	3777/22T	022383	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
LIDOCAINE ACCORD SOLUTION FOR INJECTION 10MG/ML	3778/22T	022377	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
ROSU-ASA CAPSULE, HARD 10MG/100MG	6651/22T	023200	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the

				relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSU-ASA CAPSULE, HARD 20MG/100MG	6650/22T	023201	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSU-ASA CAPSULE, HARD 5MG/100MG	6652/22T	023199	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

ALBUMAN SOLUTION FOR INFUSION 40G/L	6206/22T	023241	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUMAN SOLUTION FOR INFUSION 200G/L	6207/22T	023242	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
MELOX TABLET 7.5MG	7043/22T	017762	MEDOCHEMIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product

				Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
MELOX TABLET 15MG	7042/22T	017763	MEDOCHEMIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
CORYCARDON TABLET, FILM COATED 150/12.5MG	7637/22T	020759	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by

				the competent authority
CORYCARDON TABLET, FILM COATED 300/12.5MG	7636/22T	020760	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
CORYCARDON TABLET, FILM COATED 300/25MG	7635/22T	020761	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
FEIBA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 50U/ML	3593/22T	022344	BAXALTA INNOVATIONS GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
FEIBA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 25U/ML	3592/22T	022343	BAXALTA INNOVATIONS GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TRACHILID LOZENGE 8MG	6922/22T	020315	ENGELHARD ARZNEIMITT	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

			EL GMBH & CO. KG	CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
RUVOMINOX GEL 1%	7638/22T	013783	COSTAKIS TSISIOS & CO LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
REMETHAN TABLET, GASTRO-RESISTANT 25MG	7702/22T	010334	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
REMETHAN SUPPOSITORY 100MG	7704/22T	019883	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
REMETHAN TABLET, PROLONGED-RELEASE 100MG	7703/22T	012480	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
REMETHAN TABLET, GASTRO-RESISTANT 50MG	7701/22T	019633	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 150MG	6092/22T	023682	PHARMATHEN S.A.	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 75MG	6089/22T	023680	PHARMATHEN S.A.	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 25MG	6090/22T	023678	PHARMATHEN S.A.	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control

PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 100MG AND 150MG	6093/22T	023683	PHARMATHEN S.A.	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 50MG	6091/22T	023679	PHARMATHEN S.A.	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 100MG	6088/22T	023681	PHARMATHEN S.A.	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
MONOPROST EYE DROPS, SOLUTION 50MCG/ML	4241/22T	022828	LABORATOIRES THEA	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
SMOFKABIVEN ELECTROLYTE FREE EMULSION FOR INFUSION	3841/22T, 3842/22T, 3843/22T, 3844/22T, 3845/22T	020716	FRESENIUS KABI HELLAS A.E.	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES -

				FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
SMOFKABIVEN EMULSION FOR INFUSION	3846/22T, 3847/22T, 3848/22T, 3849/22T, 3850/22T, 3851/22T	20651	FRESENIUS KABI HELLAS A.E.	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED

				PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION	3852/22T, 3853/22T, 3854/22T, 3855/22T, 3856/22T, 3857/22T	20667	FRESENIUS KABI HELLAS A.E.	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

				test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ERELAN TABLET, FILM COATED 400MG	5698/22T, 5699/22T, 5700/22T	022911	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
IMATINIB TAD TABLET, FILM COATED 100MG	6524/22T, 6525/22T	023685	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal

				products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
IMATINIB TAD TABLET, FILM COATED 400MG	6522/22T, 6523/22T	023684	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following

				assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	3773/22T, 3774/22T, 3775/22T, 3776/22T, 4702/22T, 4703/22T, 4704/22T	023687	TEVA PHARMA BV	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	3769/22T, 3770/22T, 3771/22T, 3772/22T, 4699/22T, 4700/22T, 4701/22T	023686	TEVA PHARMA BV	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED

				PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
LIPITOR TABLET, FILM COATED 40MG	4542/22T	019491	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INSPRA TABLET, FILM COATED 25MG	4534/22T	020103	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INSPRA TABLET, FILM COATED 50MG	4533/22T	020104	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEURONTIN CAPSULE, HARD 300MG	4532/22T	017445	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEURONTIN CAPSULE, HARD 400MG	4531/22T	017446	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	4525/22T	018335	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, CHEWABLE 5MG	4541/22T	020727	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, CHEWABLE 40MG	4538/22T	020730	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE

				CHANGES - Change in the name and/or address of the marketing authorisation holder
XALATAN EYE DROPS, SOLUTION 50MCG/ML	4530/22T	020805	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	4524/22T	018334	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZOLOFT TABLET, FILM COATED 50MG	4528/22T	014677	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CELEBREX CAPSULE, HARD 200MG	4535/22T	023173	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, CHEWABLE 10MG	4540/22T	020728	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, FILM COATED 20MG	4537/22T	019490	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, FILM COATED 10MG	4536/22T	019489	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZOLOFT TABLET, FILM COATED 100MG	4529/22T	014678	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
DETRUSITOL TABLET, FILM COATED 2MG	4527/22T	023122	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EFEXOR XR PROLONGED RELEASE CAPSULES 37.5MG	4526/22T	020345	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, CHEWABLE 20MG	4539/22T	020729	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ALBUMAN SOLUTION FOR INFUSION 40G/L	6908/22T	023241	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
ALBUMAN SOLUTION FOR INFUSION 40G/L	6908/22T	023241	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products

				for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
ALBUMAN SOLUTION FOR INFUSION 200G/L	6909/22T	023242	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
LAMISIL TABLET 125MG	7207/22T	018387	NOVARTIS IRELAND LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
NUROFEN TABLET, FILM COATED 200MG	6343/22T	009734	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NUROFEN FOR CHILDREN ORAL SUSPENSION 100MG/5ML	6180/22T	013609	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLUNOL CAPSULE, HARD 100MG	7297/22T, 7298/22T	021602	PHARMA Q S.A.	B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - New certificate for a starting mater B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Deletion of certificates (in case mu
DYSPORT POWDER FOR SOLUTION FOR INJECTION 500U	7619/22T	019337	IPSEN M.E.P.E.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation

				dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
SOTILEN CAPSULE, HARD 10MG	7869/22T	019898	MEDOCHE MIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
FEMARA TABLET, FILM COATED 2.5MG	3691/22T, 3692/22T, 3693/22T, 3694/22T, 3695/22T, 3696/22T	018468	NOVARTIS IRELAND LIMITED	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and

				quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/20MG	3067/22T	023127	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/10MG	3066/22T	023126	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/40MG	3068/22T	023128	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
EZETIMIBE/MYLAN TABLET 10MG	3069/22T	023155	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
MUCOSOLVAN SOLUTION FOR INJECTION 7.5MG/ML, 2ML VIALS	7208/22T	011681	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CALCIUM-SANDOZ FORTE EFFERVESCENT TABLET 500MG	5349/22T, 5350/22T	018988	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CO-DIOVAN TABLET, FILM COATED 80/12.5MG	2612/22T, 2613/22T, 2614/22T, 2615/22T, 2616/22T, 2617/22T, 2618/22T	017851	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/int ermediate used in the manufacturi B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/int ermediate used in the manufacturi B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/int ermediate used in the manufacturing process of the active substanc
CO-DIOVAN TABLET, FILM COATED 80/12.5MG	2612/22T, 2613/22T, 2614/22T, 2615/22T, 2616/22T, 2617/22T, 2618/22T	017851	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/int ermediate used in the manufacturi B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/int ermediate used in the manufacturi B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/int ermediate used in the manufacturing process of the active substanc
DIOVAN TABLET, FILM COATED 80MG	2640/22T, 2641/22T, 2642/22T, 2643/22T, 2644/22T, 2645/22T, 2646/22T	019384	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/int ermediate used in the manufacturi B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/int ermediate used in the manufacturi B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/int ermediate used in the manufacturing process of the active substanc
DIOVAN TABLET, FILM COATED 160MG	2647/22T, 2648/22T, 2649/22T, 2650/22T, 2651/22T, 2652/22T, 2653/22T	019385	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc
DIOVAN TABLET, FILM COATED 40MG	2633/22T, 2634/22T, 2635/22T, 2636/22T, 2637/22T, 2638/22T, 2639/22T	019635	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc
CO-DIOVAN TABLET, FILM COATED 160/25MG	2626/22T, 2627/22T, 2628/22T, 2629/22T,	019477	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY

	2630/22T, 2631/22T, 2632/22T			CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc

CO-DIOVAN TABLET, FILM COATED 160/25MG	2626/22T, 2627/22T, 2628/22T, 2629/22T, 2630/22T, 2631/22T, 2632/22T	019477	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing

				process of the active substanc
CO-DIOVAN TABLET, FILM COATED 160/12.5MG	2619/22T, 2620/22T, 2621/22T, 2622/22T, 2623/22T, 2624/22T, 2625/22T	018977	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/int

				ermediate used in the manufacturing process of the active substanc
CO-DIOVAN TABLET, FILM COATED 160/12.5MG	2619/22T, 2620/22T, 2621/22T, 2622/22T, 2623/22T, 2624/22T, 2625/22T	018977	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a

				starting material/reagent/intermediate used in the manufacturing process of the active substanc
DIOVAN ORAL SOLUTION 3MG/ML	2654/22T, 2655/22T, 2656/22T, 2657/22T, 2658/22T, 2659/22T, 2660/22T	020694	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture -

				Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250IU WITH 10ML SOLVENT	5611/22T	020330	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU WITH 10ML SOLVENT	5613/22T	020332	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	5617/22T	020199	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES -

				Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
IMMUNATE 500 IU FVIII/375 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/5ML	5615/22T	020085	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
IMMUNATE 1000 IU FVIII/750 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/10ML	5616/22T	020086	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing

				authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
IMMUNATE 250 IU FVIII/190 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250IU/5ML	5614/22T	020084	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
FLEXBUMIN SOLUTION FOR INFUSION 200G/L	5620/22T	020477	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product

RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU WITH 10ML SOLVENT	5612/22T	020331	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	5619/22T	020201	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	5618/22T	020200	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new,

				updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
FLEXBUMIN SOLUTION FOR INFUSION 250G/L	5621/22T	020478	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ESOMEPRAZOLE ACCORD POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG/ML	6205/22T	022264	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MAYMETSI TABLET, FILM COATED 50MG/850MG	4313/22T	023374	TAD PHARMA GMBH	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
MAYMETSI TABLET, FILM COATED 50MG/1000MG	4314/22T	023375	TAD PHARMA GMBH	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
LIPOPEN TABLET, FILM COATED 5MG/10MG	5889/22T	023318	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIPOPEN TABLET, FILM COATED 40MG/10MG	5886/22T	023321	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIPOPEN TABLET, FILM COATED 20MG/10MG	5887/22T	023320	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIPOPEN TABLET, FILM COATED 10MG/10MG	5888/22T	023319	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the

				relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CELECOXIB ACCORD CAPSULE, HARD 200MG	6316/22T	023492	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DEANXIT TABLET, FILM COATED	6635/22T, 6636/22T	021765	LUNDBECK HELLAS A.E.,CYPRUS	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active

				substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU WITH 10ML SOLVENT	4996/22T	020331	BAXALTA INNOVATIONS GMBH	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU WITH 10ML SOLVENT	4995/22T	020332	BAXALTA INNOVATIONS GMBH	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250IU WITH 10ML SOLVENT	4997/22T	020330	BAXALTA INNOVATIONS GMBH	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes
CANDIPLAS H CREAM	7777/22T	012705	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

PAZOCTAM POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/ VIAL	5286/22T, 5287/22T	022811	SAPIENS PHARMACEUTICALS LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PRIMPERAN TABLET 10MG	7174/22T, 7175/22T	016093	SANOFI-AVENTIS GROUPE	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including

				replacement or addition)
SYMBICORT TURBUHALER POWDER FOR INHALATION 320MCG/9MCG	4016/22T	020882	ASTRAZEN ECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5MCG	4017/22T	020883	ASTRAZEN ECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	4015/22T	020881	ASTRAZEN ECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL XR TABLET, PROLONGED-RELEASE 150MG	4022/22T	020699	ASTRAZEN ECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL TABLET, FILM COATED 200MG	4025/22T	017718	ASTRAZEN ECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL TABLET, FILM COATED 100MG	4024/22T	017717	ASTRAZEN ECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL TABLET, FILM COATED 25MG	4023/22T	017716	ASTRAZEN ECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PLENDIL TABLET, PROLONGED-RELEASE 10MG	4027/22T	012025	ASTRAZEN ECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

SEROQUEL XR TABLET, PROLONGED-RELEASE 400MG	4021/22T	020359	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL XR TABLET, PROLONGED-RELEASE 300MG	4020/22T	020358	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL XR TABLET, PROLONGED-RELEASE 200MG	4019/22T	020357	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL XR TABLET, PROLONGED-RELEASE 50MG	4018/22T	020356	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SYMBICORT PRESSURISED INHALATION, SUSPENSION 160/4.5MCG/ACTUATION	4014/22T	022403	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PLENDIL TABLET, PROLONGED-RELEASE 5MG	4026/22T	012026	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TAVANIC TABLET, FILM COATED 500MG	9792/21T	019283	SANOFI-AVENTIS GROUPE	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
NOPRILAM 500 TABLET, FILM COATED (500MG/125MG)	6812/22T	018575	BIAL-PORTELA & CA, SA	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
CLOZAREM TABLET 100MG	7621/22T	019378	REMEDICA LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CLOZAREM TABLET 25MG	7622/22T	020348	REMEDICA LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material,

				reagent or excipient (when mentioned in the dossier)*
SOLPADEINE SOLUBLE TABLET	6821/22T, 6822/22T, 6823/22T	019779	OMEGA PHARMA HELLAS S.A	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
RYCARDON TABLET, FILM COATED 150MG	7634/22T	020739	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
RYCARDON TABLET, FILM COATED 300MG	7633/22T	020740	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by

				the competent authority
SORIL-MED HONEY & LEMON LOZENGE 0.60MG/1.20MG	7408/22T	022760	SAPIENS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VIDELMET TABLET, FILM COATED 50MG/1000MG	6987/22T	023639	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
VIDELMET TABLET, FILM COATED 50MG/850MG	6988/22T	023638	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
SORIL-MED HONEY & LEMON LOZENGE 0.60MG/1.20MG	3511/22T, 3512/22T	022760	SAPIENS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer

				responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ALMIRAL SUPPOSITORY 100MG	7836/22T, 7837/22T	011764	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ALMIRAL SUPPOSITORY 50MG	7838/22T, 7839/22T	011763	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DEPRIM TABLET 400MG/80MG	6393/22T, 6394/22T, 6395/22T, 6396/22T, 6397/22T, 6398/22T, 6399/22T, 6400/22T, 6401/22T, 6402/22T	019888	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificat B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specifi B.I.b.1.b B.I.b.1.b - QUALITY

				CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance w
DEPRIM ORAL SUSPENSION (200MG/40MG) /5ML	6403/22T, 6404/22T, 6405/22T, 6406/22T, 6407/22T, 6408/22T, 6409/22T, 6410/22T, 6411/22T, 6412/22T	009333	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificat B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State -

				Change of specifi B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance w
PHYSIONEAL 40 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	4827/21T	022312	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
PHYSIONEAL 40 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR	4829/21T	022314	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT -

PERITONEAL DIALYSIS 3.86%				Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
PHYSIONEAL 35 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	4831/21T	022310	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
PHYSIONEAL 40 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	4828/21T	022313	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
PHYSIONEAL 35 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	4832/21T	022309	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
PHYSIONEAL 35 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86% W/V	4830/21T	022311	BAXTER (HELLAS) EPE	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
BICAVERA SOLUTION FOR PERITONEAL	1113/22T, 1114/22T, 2692/22T	022581	FRESENIUS MEDICAL CARE	B.II.e.1.a.3 B.II.e.1.a.3 - QUALITY

DIALYSIS 1.25MMOL/L CALCIUM, 1.5% GLUCOSE			DEUTSCHLAND GMBH	CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 2.3% GLUCOSE	1111/22T, 1112/22T, 2691/22T	022582	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.II.e.1.a.3 B.II.e.1.a.3 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
BICAVERA SOLUTION FOR PERITONEAL	1109/22T, 1110/22T, 2690/22T	022580	FRESENIUS MEDICAL CARE	B.II.e.1.a.3 B.II.e.1.a.3 - QUALITY

DIALYSIS 1.25MMOL/L CALCIUM, 4.25% GLUCOSE			DEUTSCHLAND GMBH	CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.5% GLUCOSE, 1.75MMOL/L CALCIUM	1119/22T, 1120/22T, 2739/22T	023196	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.II.e.1.a.3 B.II.e.1.a.3 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
BICAVERA SOLUTION FOR PERITONEAL	1117/22T, 1118/22T, 2738/22T	023197	FRESENIUS MEDICAL CARE	B.II.e.1.a.3 B.II.e.1.a.3 - QUALITY

DIALYSIS 4.25% GLUCOSE, 1.75MMOL/L CALCIUM			DEUTSCHLAND GMBH	CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 2.3% GLUCOSE, 1.75MMOL/L CALCIUM	1115/22T, 1116/22T, 2737/22T	023198	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.II.e.1.a.3 B.II.e.1.a.3 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits
SEROPRAM TABLET, FILM COATED 20MG	5163/21T	016117	LUNDBECK HELLAS A.E.,CYPRUS	C.I.z C.I.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
SEROPRAM TABLET, FILM COATED 20MG	5163/21T	016117	LUNDBECK HELLAS A.E.,CYPRUS	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
VIBRAMYCIN TABLET, DISPERSIBLE 100MG	6870/22T, 6871/22T	013023	PFIZER HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Change in the testing frequency of specification parameter, from routine testing to skip or periodic testing
FLUDARA TABLET, FILM COATED 10MG	10373/20T, 10374/20T	020545	GENZYME EUROPE B.V.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	2331/22T	019896	MEDOCHEMIE LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	2330/22T	021944	MEDOCHEMIE LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates

				to Mod. 3.2.S or the ASMF
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	2332/22T	019897	MEDOCHEMIE LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
DULSEVIA GASTRO-RESISTANT CAPSULE, HARD 60MG	3269/22T	022815	KRKA D.D. NOVO MESTO	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DULSEVIA GASTRO-RESISTANT CAPSULE, HARD 30MG	3268/22T	022814	KRKA D.D. NOVO MESTO	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
GRANULOKINE SOLUTION FOR INJECTION 0.3MG/ML VIAL	9636/21T	019764	AMGEN EUROPE B.V.	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
GRANULOKINE SINGLEJECT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 48 MU (0,96 MG/ML)	9638/21T	019766	AMGEN EUROPE B.V.	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
GRANULOKINE SINGLEJECT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 30 MU (0,6 MG/ML)	9637/21T	019765	AMGEN EUROPE B.V.	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of

				studies to the competent authority
KANILAD TABLET, FILM COATED 100MG	3213/22T	022714	MEDOCHEMIE LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
KANILAD TABLET, FILM COATED 150MG	3214/22T	022715	MEDOCHEMIE LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
KANILAD TABLET, FILM COATED 50MG	3212/22T	022713	MEDOCHEMIE LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
KANILAD TABLET, FILM COATED 200MG	3215/22T	022716	MEDOCHEMIE LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
VOLTAREN INJECTION 75MG/3ML	5839/22T, 5840/22T, 5841/22T, 5842/22T	018434	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting

				material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele
ONDANSETRON ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	1665/22T	020718	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ONDANSETRON ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	1135/21T	020718	ACCORD HEALTHCARE S.L.U	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
ARESTON TABLET, FILM COATED 50MG	7773/22T, 7774/22T	018943	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
TROVAL TABLET, FILM COATED 80MG	7644/22T	021333	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
TROVAL TABLET, FILM COATED 160MG	7643/22T	021334	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and

				conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
TROVAL TABLET, FILM COATED 40MG	7645/22T	022510	DELORBIS PHARMACEUTICALS LTD	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/IASIS CAPSULE, HARD 5MG	5300/22T	021605	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/IASIS CAPSULE, HARD 10MG	5299/22T	021606	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VOLTAREN TABLET, GASTRO-RESISTANT 50MG	3478/22T	018455	NOVARTIS IRELAND LIMITED	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
DONEPEZIL ACCORD TABLET, FILM COATED 5MG	4991/22T	021471	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
DONEPEZIL ACCORD TABLET, FILM COATED 10MG	4992/22T	021472	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
LIPITOR TABLET, FILM COATED 40MG	7977/21T	019491	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ATORVASTATIN UPJOHN TABLET, FILM COATED 40MG	7973/21T	021891	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ATORVASTATIN UPJOHN TABLET, FILM COATED 80MG	7974/21T	021892	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LIPITOR TABLET, FILM COATED 10MG	7975/21T	019489	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LIPITOR TABLET, FILM COATED 20MG	7976/21T	019490	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DEXAFREE EYE DROPS, SOLUTION 1MG/ML	4171/22T, 4172/22T	021770	LABORATOIRES THEA	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TRIACOR TABLET, PROLONGED-RELEASE 5MG/5MG	7209/22T	019492	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient -

				European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIACOR TABLET, PROLONGED-RELEASE 5MG/5MG	7082/22T, 7083/22T, 7084/22T	019492	SANOFI-AVENTIS GROUPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the

				approved dossier - Re-test period/storage period -
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	9767/21T	020032	ALLERGAN PHARMACEUTICALS IRELAND	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
VOLTAREN FOR CHILDREN SUPPOSITORY 12.5MG	5606/22T	018454	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
VOLTAREN SUPPOSITORY 100MG	5607/22T	018400	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
BUSCOFEM EXTRA TABLET, FILM COATED 400MG/100MG	3570/21T	023552	SANOFI AVENTIS AEBE	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
VOLTAREN TABLET, GASTRO-RESISTANT 50MG	3209/22T	018455	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer,

				batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
VOLTAREN SUPPOSITORY 50MG	1876/22T	018443	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
FEMI TABLET 0.250MG/0.035MG	5821/22T, 5822/22T	023355	ITF HELLAS A.E.	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
VOLTAREN SUPPOSITORY 50MG	7098/21T	018443	NOVARTIS IRELAND LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet

				due to new quality, preclinical, clinical or pharmacovigilance data
VOLTAREN FOR CHILDREN SUPPOSITORY 12.5MG	7099/21T	018454	NOVARTIS IRELAND LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VOLTAREN TABLET, GASTRO-RESISTANT 50MG	7094/21T	018455	NOVARTIS IRELAND LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VOLTAREN SUPPOSITORY 100MG	7097/21T	018400	NOVARTIS IRELAND LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VOLTAREN SR SUSTAINED RELEASE TABLETS 75MG	7095/21T	018459	NOVARTIS IRELAND LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VOLTAREN RETARD SUSTAINED RELEASE TABLETS 100MG	7101/21T	018444	NOVARTIS IRELAND LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VOLTAREN D TABLET, DISPERSIBLE 50MG	7100/21T	018457	NOVARTIS IRELAND LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VOLTAREN INJECTION 75MG/3ML	7096/21T	018434	NOVARTIS IRELAND LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FORMOPEN INHALATION POWDER, PRE-DISPENSED 12MCG/BLISTER	6537/22T, 6538/22T, 6539/22T	020596	ELPEN PHARMACEUTICAL CO INC	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
VOLTAREN SUPPOSITORY 50MG	6272/20T	018443	NOVARTIS IRELAND LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data.
VOLTAREN TABLET, GASTRO-RESISTANT 50MG	6270/20T	018455	NOVARTIS IRELAND LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
VOLTAREN SUPPOSITORY 100MG	6273/20T	018400	NOVARTIS IRELAND LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
VOLTAREN SR SUSTAINED RELEASE TABLETS 75MG	6276/20T	018459	NOVARTIS IRELAND LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
VOLTAREN RETARD SUSTAINED RELEASE TABLETS 100MG	6275/20T	018444	NOVARTIS IRELAND LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
VOLTAREN D TABLET, DISPERSIBLE 50MG	6274/20T	018457	NOVARTIS IRELAND LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
VOLTAREN INJECTION 75MG/3ML	6271/20T	018434	NOVARTIS IRELAND LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.

LYSOSPRAY OROMUCOSAL SPRAY 2.5MG/ACTUATION	6069/20T	022023	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
LYSOSPRAY OROMUCOSAL SPRAY 2.5MG/ACTUATION	2983/20T	022023	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
ISOPTO-MAXITROL EYE OINTMENT	6250/22T	017327	NOVARTIS IRELAND LIMITED	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
OXIS TURBUHALER POWDER FOR INHALATION 4.5MCG/DOSE	6621/22T, 6622/22T	017419	ASTRAZENECA AB	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State -

				Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
OXIS TURBUHALER POWDER FOR INHALATION 9MCG/DOSE	6623/22T, 6624/22T	017420	ASTRAZENECA AB	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
DORZOTIM EYE DROPS, SOLUTION	4961/22T, 4962/22T	021075	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the

				relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DORZON EYE DROPS, SOLUTION 2%	4898/22T	020543	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TIENAM POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	5104/22T	021719	MERCK SHARP & DOHME BV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TOBRADEX EYE DROPS, SUSPENSION 0,1% w/v + 0,3% w/v	7986/20T	017319	NOVARTIS IRELAND LIMITED	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/500MCG	6436/22T	022632	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AUGMENTIN MIXED FRUIT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	6440/22T	022824	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	6437/22T	018617	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/250MCG	6434/22T	022631	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/100MCG	6435/22T	022630	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	6425/22T	016176	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	6431/22T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	6430/22T	018647	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	6423/22T	018618	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	6428/22T	017527	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROXAT TABLET, FILM COATED 20MG	6433/22T	014178	GLAXOSMITHKLINE	A.1 A.1 - ADMINISTRATIVE

			(IRELAND) LIMITED	CHANGES - Change in the name and/or address of the marketing authorisation holder
VALTREX TABLET, FILM COATED 500MG	6432/22T	016180	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	6424/22T	016177	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	6422/22T	016178	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AUGMENTIN TABLET, FILM COATED 500MG/125MG	6439/22T	012656	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	6427/22T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	6429/22T	020252	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
WELLBUTRIN XR MODIFIED-RELEASE TABLET 300MG	6442/22T	020249	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
WELLBUTRIN XR MODIFIED-RELEASE TABLET 150MG	6426/22T	020248	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
AVODART CAPSULE, SOFT 0.5MG	6438/22T	019719	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AUGMENTIN TABLET, FILM COATED 1G	6441/22T	019515	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VINBLASTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	7412/22T	012083	PFIZER HELLAS AE	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)
PRIMPERAN TABLET 10MG	6145/22T	016093	SANOFI-AVENTIS GROUPE	B.II.f.1.a.1 B.II.f.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Reduction of the shelf life of the finished product - As packaged for sale
APO-GO PEN SOLUTION FOR INJECTION 10MG/ML	6518/21T, 6519/21T, 6520/21T	021473	ITF HELLAS A.E.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
APO-GO PFS SOLUTION FOR INFUSION 5MG/ML IN PREFILLED SYRINGE	6521/21T, 6522/21T, 6523/21T	021474	ITF HELLAS A.E.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
IMODIUM ORIGINAL CAPSULE, HARD 2MG	1807/22T, 1808/22T, 1809/22T, 1810/22T, 1811/22T, 1812/22T	006139	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products B.II.b.1.c B.II.b.1.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Other variation B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s) B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finis B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage co
NEURONTIN CAPSULE, HARD 300MG	9426/21T, 9427/21T, 9428/21T	017445	UPJOHN HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.b.2.a B.II.b.2.a

				- QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible
NEURONTIN CAPSULE, HARD 400MG	9423/21T, 9424/21T, 9425/21T	017446	UPJOHN HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible
BUDENOFALK UNO GASTRO-RESISTANT GRANULES 9MG	5846/22T	022433	DR. FALK PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
IMODIUM ORIGINAL CAPSULE, HARD 2MG	3703/22T	006139	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
FLUOXETINE AUROBINDO CAPSULE, HARD 20MG	6361/22T	023333	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.4 B.III.1.a.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material)
VILDAGLIPTIN PHARMATHEN TABLET 50MG	5986/22T	023063	PHARMATHEN S.A.	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold

				increase compared to the originally approved batch size
LATANOPROST DEMO EYE DROPS, SOLUTION 50MCG/ML	4261/22T	022516	DEMO S.A.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	7211/22T, 7212/22T, 7213/22T, 7214/22T, 7215/22T, 7216/22T	020968	IPSEN PHARMA	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of

				manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
DELSIMET TABLET, FILM COATED 50MG/1000MG	6985/22T	023402	DELORBIS PHARMACEUTICALS LTD	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
DELSIMET TABLET, FILM COATED 50MG/850MG	6986/22T	023401	DELORBIS PHARMACEUTICALS LTD	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
MEROPENEM VENUS POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/VIAL	58/21T	021663	VENUS PHARMA GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
MEROPENEM VENUS POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	57/21T	021662	VENUS PHARMA GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
MEROPENEM VENUS POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/VIAL	4207/21T	021663	VENUS PHARMA GMBH	B.II.f.1.b.3 B.II.f.1.b.3 - QUALITY CHANGES - FINISHED

				PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)
MEROPENEM VENUS POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	4206/21T	021662	VENUS PHARMA GMBH	B.II.f.1.b.3 B.II.f.1.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)
ZINDOLIN TABLET, FILM COATED 250MG	6906/22T	013916	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ZINDOLIN TABLET, FILM COATED 500MG	6907/22T	020026	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CLINIMIX N14G30E SOLUTION FOR INFUSION	3845/21T, 3846/21T, 3847/21T	018591	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - Eur B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
REZAVIR TABLET, FILM COATED 150MG	6111/22T, 6112/22T	022547	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY

				CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
REZAVIR TABLET, FILM COATED 400MG	6107/22T, 6108/22T	022549	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
REZAVIR TABLET, FILM COATED 75MG	6113/22T, 6114/22T	022546	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting

				material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
REZAVIR TABLET, FILM COATED 800MG	6103/22T, 6104/22T	022551	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
REZAVIR TABLET, FILM COATED 600MG	6105/22T, 6106/22T	022550	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY

				CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
REZAVIR TABLET, FILM COATED 300MG	6109/22T, 6110/22T	022548	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting

				material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	736/21T	017108	PFIZER HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	737/21T	017107	PFIZER HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/VIAL (100IU/ML)	3482/22T, 3483/22T, 3484/22T, 3485/22T	020943	OCTAPHARMA (IP) SPRL	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a

				biological reference preparation not covered by an approved protocol B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/VIAL(100IU/ML)	3486/22T, 3487/22T, 3488/22T, 3489/22T	020944	OCTAPHARMA (IP) SPRL	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	703/22T	020206	GRIFOLS DEUTSCHLAND GMBH.	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer

				(including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
RIBAVIRIN AUROBINDO TABLET, FILM COATED 200MG	9369/21T	022274	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
EUTHYROX TABLET 50MCG	6043/22T	019425	MERCK A E HELLAS	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
EUTHYROX TABLET 100MCG	6042/22T	019426	MERCK A E HELLAS	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and

				quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
TICOVAC JUNIOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.25ML/DOSE	5150/22T, 5151/22T	023267	PFIZER HELLAS AE	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
TICOVAC SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.5ML/DOSE	5152/22T, 5153/22T	023266	PFIZER HELLAS AE	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of

				Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
AMLODIPIN ACCORD TABLET 10MG	5706/22T	022810	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPIN ACCORD TABLET 5MG	5707/22T	022809	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR

				or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	4610/22T, 4611/22T, 4612/22T	020206	GRIFOLS DEUTSCHLAND GMBH.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
GYNOFLORAN CAPSULE, HARD 50MG	4861/22T, 4862/22T	012702	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GYNOFLORAN CAPSULE, HARD 150MG	4859/22T, 4860/22T	012703	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites

				for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TREBON-N LOZENGE 600MG	6733/22T	022615	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TREBON-N GRANULES FOR ORAL SUSPENSION 600MG/SACHET	6734/22T	022102	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MAYMETSI TABLET, FILM COATED 50MG/1000MG	6521/22T	023375	TAD PHARMA GMBH	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
MAYMETSI TABLET, FILM COATED 50MG/850MG	6520/22T	023374	TAD PHARMA GMBH	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
QUELORAN TABLET, PROLONGED-RELEASE 200MG	9625/21T	023409	PHARMATHEN S.A.	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
QUELORAN TABLET, PROLONGED-RELEASE 50MG	9623/21T	023407	PHARMATHEN S.A.	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
QUELORAN TABLET, PROLONGED-RELEASE 400MG	9627/21T	023411	PHARMATHEN S.A.	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
QUELORAN TABLET, PROLONGED-RELEASE 150MG	9624/21T	023408	PHARMATHEN S.A.	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
QUELORAN TABLET, PROLONGED-RELEASE 300MG	9626/21T	023410	PHARMATHEN S.A.	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
VAGIFEM FILM COATED VAGINAL TABLETS 10MCG	5525/22T	020906	NOVO NORDISK A/S	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to

				an approved test procedure
MEROPENEM/KABI POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG	2711/22T	020996	FRESENIUS KABI HELLAS A.E.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
MEROPENEM/KABI POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG	2712/22T	020997	FRESENIUS KABI HELLAS A.E.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
LIPTRUZET TABLET, FILM COATED 10MG/40MG	6415/22T	022098	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPTRUZET TABLET, FILM COATED 10MG/20MG	6414/22T	022097	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPTRUZET TABLET, FILM COATED 10MG/80MG	6416/22T	022099	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPTRUZET TABLET, FILM COATED 10MG/10MG	6413/22T	022096	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EZETROL TABLET 10MG	6417/22T	019668	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FUSIDIC ACID/BETAMETHASONE VALERATE PHARMASCIENCE INTERNATIONAL CREAM (20MG/1MG)/G	6013/22T	022726	PHARMASCIENCE INTERNATIONAL LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	2386/22T, 2387/22T, 2388/22T	019523	SANOFI PASTEUR.	B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	6058/21T	019724	MERCK SHARP & DOHME BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DIAZEPAM ACCORD TABLET 10MG	616/22T	023467	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
DIAZEPAM ACCORD TABLET 5MG	615/22T	023466	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient -

				European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
SEROQUEL XR TABLET, PROLONGED-RELEASE 50MG	5778/21T	020356	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL XR TABLET, PROLONGED-RELEASE 150MG	5779/21T	020699	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL XR TABLET, PROLONGED-RELEASE 200MG	5782/21T	020357	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data
SEROQUEL XR TABLET, PROLONGED-RELEASE 300MG	5781/21T	020358	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL XR TABLET, PROLONGED-RELEASE 400MG	5780/21T	020359	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL TABLET, FILM COATED 25MG	5785/21T	017716	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL TABLET, FILM COATED 100MG	5783/21T	017717	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SEROQUEL TABLET, FILM COATED 200MG	5784/21T	017718	ASTRAZENECA AB	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
EPHEDRINE SINTETICA SOLUTION FOR INJECTION 50MG/ML	6478/22T, 6479/22T, 6480/22T	023427	SINTETICA GMBH	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes

EPHEDRINE SINTETICA SOLUTION FOR INJECTION 10MG/ML	6481/22T, 6482/22T, 6483/22T	023426	SINTETICA GMBH	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
GABAPENTIN ACCORD CAPSULE, HARD 300MG	7051/22T	022566	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GABAPENTIN ACCORD CAPSULE, HARD 400MG	7050/22T	022567	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a

				starting material, reagent or excipient (when mentioned in the dossier)*
DELSIMET TABLET, FILM COATED 50MG/1000MG	4889/22T	023402	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DELSIMET TABLET, FILM COATED 50MG/850MG	4890/22T	023401	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
APONIL TABLET 100MG	7041/22T	017417	MEDOCHEMIE LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
TRICEF POWDER FOR ORAL SUSPENSION 100MG/5ML	6372/22T	019143	BIAL-PORTELA & CA, SA	B.II.b.4.b B.II.b.4.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 36MG	1323/22T	021506	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EZETIMIBE SANDOZ TABLET 10MG	1325/22T	022118	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 5MG	1319/22T	null	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 20MG	1321/22T	null	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 18MG	1322/22T	021505	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 54MG	1324/22T	021507	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 10MG	1320/22T	null	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
APO-GO PEN SOLUTION FOR INJECTION 10MG/ML	3233/22T	021473	ITF HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
APO-GO PFS SOLUTION FOR INFUSION 5MG/ML IN PREFILLED SYRINGE	3234/22T	021474	ITF HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SOLPADEINE MAX SOLUBLE EFFERVESCENT TABLET 500MG/30MG/12.8MG	1598/22T, 1599/22T	022825	OMEGA PHARMA HELLAS S.A	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance

				For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NEPHROTECT SOLUTION FOR INFUSION 10%	4175/22T, 4176/22T, 4177/22T, 4178/22T, 4179/22T	020261	FRESENIUS KABI HELLAS AE	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
FLIXOTIDE DISKUS POWDER FOR INHALATION 250MCG	5605/22T	019606	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
SERETIDE EVOHALER PRESSURISED INHALATION, SUSPENSION 25MCG/50MCG	5603/22T	019553	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
FLIXOTIDE DISKUS POWDER FOR INHALATION 100MCG	5604/22T	019556	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the

				specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	5852/22T	022913	OCTAPHARMA (IP) SPRL	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 1000IU	5851/22T	022914	OCTAPHARMA (IP) SPRL	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol
LAMOTRIX TABLET 25MG	4747/22T	018540	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMOTRIX TABLET 100MG	4745/22T	018541	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMOTRIX TABLET 50MG	4746/22T	018538	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMOTRIX TABLET 200MG	4744/22T	018539	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALENDRONIC ACID ACCORD TABLET 70MG	5692/22T	020928	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or

				addition of a supplier
ALLUZIENCE SOLUTION FOR INJECTION 200 SPEYWOOD UNITS/ML	1799/22T	023486	IPSEN PHARMA	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
FLAGYL TABLET 400MG	762/22T, 763/22T, 764/22T, 765/22T, 766/22T, 767/22T	019552	SANOFI-AVENTIS GROUPE	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsol B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its correspo B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.a B.II.d.1.a

				- QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits
FLAGYL TABLET 400MG	549/22T	019552	SANOFI-AVENTIS GROUPE	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
FLAGYL TABLET 400MG	873/22T, 874/22T, 875/22T, 876/22T, 877/22T, 878/22T	019552	SANOFI-AVENTIS GROUPE	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces

				B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finis B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f
FLAGYL TABLET 400MG	768/22T, 769/22T	019552	SANOFI-AVENTIS GROUPE	B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting

				materials and immediate packaging materials
TAMSULOSIN AUROBINDO TABLET, PROLONGED-RELEASE 0.4MG	2510/22T	023574	AUROBINDO PHARMA (MALTA) LIMITED	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
CANDIPLAS H CREAM	6873/22T	012705	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LYSOSPRAY OROMUCOSAL SPRAY 2.5MG/ACTUATION	273/22T	022023	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance

				system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
BUSCOFEM CAPSULE, SOFT 400MG	275/22T	022424	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
BUSCOFEM EXTRA TABLET, FILM COATED 400MG/100MG	274/22T	023552	SANOFI AVENTIS AEBE	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 200MCG	6044/22T	019505	NOVARTIS IRELAND LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 400MCG	6045/22T	019506	NOVARTIS IRELAND LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
EFAVIRENZ AUROBINDO TABLET, FILM COATED 600MG	3858/22T	022108	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
VIZITRAV EYE DROPS, SOLUTION 40MCG/ML	4029/22T	023221	BAUSCH + LOMB IRELAND LIMITED	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
METFORMIN ACCORD TABLET, FILM COATED 500MG	3927/22T	023548	ACCORD HEALTHCARE S.L.U	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
METFORMIN ACCORD TABLET, FILM COATED 500MG	4396/22T, 4397/22T, 4398/22T, 4399/22T	023548	ACCORD HEALTHCARE S.L.U	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes

METFORMIN ACCORD TABLET, FILM COATED 850MG	4012/22T, 4013/22T	023549	ACCORD HEALTHCARE S.L.U	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
GENEMENT TABLET, FILM COATED 20MG	4856/22T	023124	GENEPHARM SA	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
GENEMENT TABLET, FILM COATED 5MG	4857/22T	023123	GENEPHARM SA	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
SYNTOCINON CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTIO 10 IU/ML	6151/21T	018420	MYLAN IRE HEALTHCARE LIMITED	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	1957/22T, 1958/22T, 1959/22T	023688	TEVA PHARMA BV	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	1789/22T, 1790/22T, 1791/22T, 1792/22T	023687	TEVA PHARMA BV	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification

				parameters and/or limits of the immediate packaging of the finished product - Other changes
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	1793/22T, 1794/22T, 1795/22T, 1796/22T	023686	TEVA PHARMA BV	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
NUROFEN EXPRESS CAPSULE, SOFT 400MG	8457/21T	021486	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	5126/22T	023686	TEVA PHARMA BV	B.II.e.3.a B.II.e.3.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	5124/22T	023688	TEVA PHARMA BV	B.II.e.3.a B.II.e.3.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure

PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	5125/22T	023687	TEVA PHARMA BV	B.II.e.3.a B.II.e.3.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure
ERMYCED POWDER FOR ORAL SUSPENSION 125MG/5ML	4712/22T	012392	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ERMYCED POWDER FOR ORAL SUSPENSION 250MG/5ML	4711/22T	012391	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SILDENAFIL MYLAN TABLET, FILM COATED 100MG	4978/22T	023105	MYLAN IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
SILDENAFIL MYLAN TABLET, FILM COATED 25MG	4980/22T	023103	MYLAN IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
SILDENAFIL MYLAN TABLET, FILM COATED 50MG	4979/22T	023104	MYLAN IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
SILDENAFIL MYLAN TABLET, FILM COATED 100MG	2399/22T	023105	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products

SILDENAFIL MYLAN TABLET, FILM COATED 100MG	5763/22T, 5764/22T	023105	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SILDENAFIL MYLAN TABLET, FILM COATED 25MG	5767/22T, 5768/22T	023103	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SILDENAFIL MYLAN TABLET, FILM COATED 50MG	5765/22T, 5766/22T	023104	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VOLTAREN D TABLET, DISPERSIBLE 50MG	6432/20T, 6433/20T, 6434/20T, 6435/20T, 6436/20T, 6437/20T, 6438/20T, 6439/20T, 6440/20T, 6441/20T, 6442/20T, 6443/20T, 6444/20T, 6445/20T, 6446/20T	018457	NOVARTIS IRELAND LIMITED	B.I.b.2 e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.I.b.1 z) Change in the specification parameters and/or limits of an active

				substance, starting material/intermediate/reagent used in the man B.I.b.1 d) Deletion of a nonsignificant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1 b) Tightening of specification limits B.I.a.1 f) Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/test B.I.a.1 b) Introduction of a manufacturer of the active substance supported by an ASMF A.4 Change in the name and/or address of a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a sup
VALSIMIA TABLET, FILM COATED 10MG/160MG	5598/22T	022441	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 -

				Implementation of wording agreed by the competent authority
VALSIMIA TABLET, FILM COATED 5MG/80MG	5597/22T	022439	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VALSIMIA TABLET, FILM COATED 5MG/160MG	5596/22T	022440	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
STORILAT R TABLET, PROLONGED-RELEASE 400MG	4493/22T, 4494/22T, 4495/22T	014793	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes
MUCOSOLVAN PROLONGED RELEASE CAPSULES 75MG	4168/20T	019781	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 z) Other variation
MUCOSOLVAN ORAL GUM 15MG	4165/20T	020696	SANOFI AVENTIS AEBE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 z) Other variation
MUCOSOLVAN SOLUTION FOR INJECTION 7.5MG/ML, 2ML VIALS	4164/20T	011681	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.

				C.I.4 z) Other variation
MUCOSOLVAN SYRUP 15MG/5ML	4167/20T	011682	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 z) Other variation
MUCOSOLVAN SYRUP 30MG/5ML	4166/20T	021127	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 z) Other variation
BORTEZOMIB STADA SOLUTION FOR INJECTION 2.5MG/ML	1261/22T	023431	STADA ARZNEIMITTEL AG	B.II.e.5.c B.II.e.5.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/ immunological medicinal products
VALSIMIA TABLET, FILM COATED 5MG/160MG	4966/22T	022440	ELPEN PHARMACEUTICAL CO INC	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
VALSIMIA TABLET, FILM COATED 10MG/160MG	4621/22T	022441	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate
VALSIMIA TABLET, FILM COATED 5MG/80MG	4620/22T	022439	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate
VALSIMIA TABLET, FILM COATED 5MG/160MG	4619/22T	022440	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate
VALSIMIA TABLET, FILM COATED 10MG/160MG	4592/22T	022441	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VALSIMIA TABLET, FILM COATED 5MG/80MG	4594/22T	022439	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VALSIMIA TABLET, FILM COATED 5MG/160MG	4593/22T	022440	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the

				relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VALSIMIA TABLET, FILM COATED 10MG/160MG	4622/22T, 4623/22T	022441	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VALSIMIA TABLET, FILM COATED 5MG/80MG	4626/22T, 4627/22T	022439	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

VALSIMIA TABLET, FILM COATED 5MG/160MG	4624/22T, 4625/22T	022440	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ARICEPT TABLET, FILM COATED 5MG	8302/21T	017824	PFIZER HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ARICEPT TABLET, FILM COATED 10MG	8303/21T	017825	PFIZER HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material,

				reagent or excipient (when mentioned in the dossier)*
ARICEPT TABLET, FILM COATED 10MG	8558/21T, 8559/21T	017825	PFIZER HELLAS AE	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ARICEPT TABLET, FILM COATED 5MG	8556/21T, 8557/21T	017824	PFIZER HELLAS AE	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product,

				packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ARICEPT TABLET, FILM COATED 5MG	6281/22T, 6282/22T, 6283/22T, 6284/22T, 6285/22T	017824	PFIZER HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ARICEPT TABLET, FILM COATED 10MG	6276/22T, 6277/22T, 6278/22T, 6279/22T, 6280/22T	017825	PFIZER HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NETENAX EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 3MG/ML	8460/21T	023365	NEWLINE PHARMA, S.L.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
NETENAX EYE DROPS, SOLUTION 3MG/ML	8461/21T	023364	NEWLINE PHARMA, S.L.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for

				Nationally Authorised Products
DELSIMET TABLET, FILM COATED 50MG/1000MG	3918/22T	023402	DELORBIS PHARMACEUTICALS LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
DELSIMET TABLET, FILM COATED 50MG/850MG	3917/22T	023401	DELORBIS PHARMACEUTICALS LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
QLAIRA TABLET, FILM COATED	1259/22T	020525	BAYER HELLAS ABEE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of

				Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
REMETHAN SUPPOSITORY 100MG	6248/22T, 6249/22T	019883	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+250)MCG/DOSE	6529/22T, 6530/22T, 6531/22T	020861	ELPEN PHARMACEUTICAL CO INC	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the

				finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+500)MCG/DOSE	6526/22T, 6527/22T, 6528/22T	020862	ELPEN PHARMACEUTICAL CO INC	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant

				specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+100)MCG/DOSE	6532/22T, 6533/22T, 6534/22T	021399	ELPEN PHARMACEUTICAL CO INC	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the

				finished product - Other changes
REPRAT TABLET, GASTRO-RESISTANT 40MG	6116/22T	020927	DELORBIS PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
REPRAT TABLET, GASTRO-RESISTANT 20MG	6117/22T	020926	DELORBIS PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
REPRAT GAST TABLET, GASTRO-RESISTANT 20MG	6115/22T	021618	DELORBIS PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
FLOXAVAL TABLET, FILM COATED 250MG	6095/22T	021386	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLOXAVAL TABLET, FILM COATED 500MG	6094/22T	021387	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MATRIFEN PATCH, TRANSDERMAL 75MCG/HOUR	5253/21T	020214	TAKEDA PHARMA A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a

				Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
MATRIFEN PATCH, TRANSDERMAL 12MCG/HOUR	5250/21T	020212	TAKEDA PHARMA A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
MATRIFEN PATCH, TRANSDERMAL 100MCG/HOUR	5254/21T	020213	TAKEDA PHARMA A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety

				Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
MATRIFEN PATCH, TRANSDERMAL 25MCG/HOUR	5251/21T	020215	TAKEDA PHARMA A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
MATRIFEN PATCH, TRANSDERMAL 50MCG/HOUR	5252/21T	020216	TAKEDA PHARMA A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent

				authority that require additional minor assessment, e.g. translations are not yet agreed upon.
BETAC TABLET, FILM COATED 20MG	9347/21T	017976	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BETAC TABLET, FILM COATED 10MG	9346/21T	021867	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LOSADRAC TABLET, FILM COATED 50MG	7290/22T, 7291/22T	022185	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site
AUGMENTIN POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	3755/20T	019702	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
ALFOXAN CAPSULE, HARD 250MG	7326/22T	019924	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
ALFOXAN 500 TABLET, FILM COATED 500MG	7325/22T	014417	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
ALFOXAN SYRUP 50MG/5ML	7324/22T	016070	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
ZYKALOR TABLET 30MG	5223/22T	022285	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ZYKALOR TABLET 20MG	5224/22T	022284	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ZYKALOR TABLET 5MG	5227/22T	022281	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product -

				Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ZYKALOR TABLET 15MG	5225/22T	022283	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ZYKALOR TABLET 10MG	5226/22T	022282	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FORMOPEN INHALATION POWDER, PRE-DISPENSED 12MCG/BLISTER	7253/22T, 7254/22T	020596	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.b.2.b B.I.b.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/intermediate, if an alternative test procedure is already authorised.
FORMOPEN INHALATION POWDER, PRE-DISPENSED 12MCG/BLISTER	5297/22T, 5298/22T	020596	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance -

				Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TESTOGEL GEL 25MG	8052/20T	020590	LABORATOIRES BESINS INTERNATIONAL	A.5 a) The activities for which the manufacturer/importer is responsible include batch release
TESTOGEL GEL 50MG	8051/20T	020520	LABORATOIRES BESINS INTERNATIONAL	A.5 a) The activities for which the manufacturer/importer is responsible include batch release
TESTOGEL GEL 25MG	4371/20T, 4372/20T	020590	LABORATOIRES BESINS INTERNATIONAL	A.2 b) for Nationally Authorised Products C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
TESTOGEL GEL 50MG	4369/20T, 4370/20T	020520	LABORATOIRES BESINS INTERNATIONAL	A.2 b) for Nationally Authorised Products C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation

VALORAN POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	7282/22T	012779	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VALORAN POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	7281/22T	012778	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VALORAN POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G/VIAL	7280/22T	023192	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
EVEROLIMUS/PHARMAZAC TABLET 5MG	33/22T, 34/22T, 35/22T, 36/22T, 37/22T, 38/22T	023310	PHARMAZAC S.A.	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing

				process of the B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
EVEROLIMUS/PHARMAZA C TABLET 2.5MG	27/22T, 28/22T, 29/22T, 30/22T, 31/22T, 32/22T	023302	PHARMAZA C S.A.	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.a.2.e B.I.a.2.e - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
EVEROLIMUS/PHARMAZAC TABLET 10MG	39/22T, 40/22T, 41/22T, 42/22T, 43/22T, 44/22T	023311	PHARMAZAC S.A.	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the

				manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
BACTROBAN CREAM 2%(W/W)	6272/22T, 6273/22T	022917	GLAXOSMITHKLINE (IRELAND) LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
ZOBRAL TABLET, FILM COATED 5MG	7188/22T, 7189/22T, 7190/22T, 7191/22T, 7192/22T, 7193/22T, 7194/22T, 7195/22T, 7196/22T, 7197/22T, 7198/22T, 7199/22T, 7200/22T, 7201/22T, 7202/22T, 7203/22T, 7204/22T	021149	DELORBIS PHARMACEUTICALS LTD	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monogra B.II.c.1.b B.II.c.1.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or

				limits of an excipient - Addition of a new specification parameter to B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.1.z B.II.c.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Other changes B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification
MOXARIN POWDER FOR INJECTION 1G/VIAL	7047/22T	013764	CODAL SYNTO LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
MOXARIN POWDER FOR INJECTION 500MG/VIAL	7048/22T	013766	CODAL SYNTO LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for

				the finished product - Other changes to a test procedure (including replacement or addition)
PEROFEN TABLET, FILM COATED 200MG	7265/22T	019923	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
PEROFEN TABLET, COATED 200MG	7264/22T	008593	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
PEROFEN 400 TABLET, FILM COATED 400MG	7263/22T	008597	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY,

				EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
PEROFEN TABLET, COATED 400MG	7262/22T	008595	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
PEROFEN TABLET, FILM COATED 600MG	7261/22T	014136	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	4555/22T	019160	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	4553/22T	019161	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	4556/22T	019159	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	4554/22T	019744	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SINGULAIR TABLET, CHEWABLE 4MG	1553/21T, 1554/21T	019291	N.V. ORGANON	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible

				do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
INEGY TABLET 10MG/80MG	1549/21T, 1550/21T	020132	N.V. ORGANON	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ARCOXIA TABLET, FILM COATED 120MG	1541/21T, 1542/21T	019446	N.V. ORGANON	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished

				product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
INEGY TABLET 10MG/40MG	1547/21T, 1548/21T	020131	N.V. ORGANON	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

REMERON TABLET, FILM COATED 30MG	1551/21T, 1552/21T	017755	N.V. ORGANON	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ARCOXIA TABLET, FILM COATED 60MG	1537/21T, 1538/21T	019444	N.V. ORGANON	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for

				batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
INEGY TABLET 10MG/10MG	1543/21T, 1544/21T	020129	N.V. ORGANON	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ARCOXIA TABLET, FILM COATED 90MG	1539/21T, 1540/21T	019445	N.V. ORGANON	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of

				manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
INEGY TABLET 10MG/20MG	1545/21T, 1546/21T	020130	N.V. ORGANON	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SEROXAT TABLET, FILM COATED 20MG	5261/21T	014178	GLAXOSMITHKLINE (IRELAND) LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
EBASTEL TABLET, FILM COATED 10MG	4893/22T	019242	ALMIRALL S.A.	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
REMYCIN TABLET, FILM COATED 100MG	6344/22T	014413	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LIPOCOMB CAPSULE, HARD 10MG/10MG	3281/22T	023608	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
LIPOCOMB CAPSULE, HARD 20MG/10MG	3282/22T	023609	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
URICHOFEB TABLET, FILM COATED 80MG	5060/22T	022734	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF

URICHOFEB TABLET, FILM COATED 120MG	5059/22T	022735	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
TRANEXAMIC ACID ACCORD SOLUTION FOR INJECTION 100MG/ML	5708/22T, 5709/22T, 5710/22T, 5711/22T	022786	ACCORD HEALTHCARE S.L.U	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
HYDROXYCHLOROQUINE SULFATE ACCORD TABLET, FILM COATED 200MG	8738/20T	023189	ACCORD HEALTHCARE S.L.U	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation

HYDROXYCHLOROQUINE SULFATE ACCORD TABLET, FILM COATED 200MG	3273/22T	023189	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
COSOPT IMULTI EYE DROPS, SOLUTION (20MG/5MG)/ML	6489/21T	022891	VIANEX S.A	B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes
STAMARIL POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION IN PREFILLED SYRINGE	5022/22T	023176	SANOFI PASTEUR.	B.II.c.1.z B.II.c.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Other changes
MIFEGYNE TABLET 200MG	9679/21T, 9680/21T, 9681/21T, 9682/21T, 9683/21T	022983	EXELGYN	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance -

				Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the
TAFLOTAN EYE DROPS, SOLUTION 15MCG/ML	383/22T, 2707/22T, 2708/22T, 2709/22T	022835	VIANEX S.A	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally

				Authorised Products
BRADIREM TABLET, FILM COATED 5MG	6011/22T, 6012/22T	022611	REMEDICA LTD	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits
BRADIREM TABLET, FILM COATED 7.5MG	6009/22T, 6010/22T	022612	REMEDICA LTD	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification

				parameter (e.g. deletion of an obsolete parameter) B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits
NIMBEX SOLUTION FOR INJECTION OR INFUSION 2MG/ML	6144/22T	018088	ASPEN PHARMA TRADING LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
ALMIRAL SOLUTION FOR INJECTION & INFUSION 75MG/3ML	7044/22T, 7045/22T	012858	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
CHLOROQUINE PHOSPHATE TABLET, COATED 250MG	4491/22T, 4492/22T	012096	REMEDICA LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active

				substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
ABSTRAL TABLET, SUBLINGUAL 200MCG	2729/22T	20605	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ABSTRAL TABLET, SUBLINGUAL 300MCG	2728/22T	020606	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended

				to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ABSTRAL TABLET, SUBLINGUAL 800MCG	2725/22T	020609	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ABSTRAL TABLET, SUBLINGUAL 400MCG	2727/22T	020607	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ABSTRAL TABLET, SUBLINGUAL 100MCG	2730/22T	020604	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

ABSTRAL TABLET, SUBLINGUAL 600MCG	2726/22T	020608	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
CLARIPEN GRANULES FOR ORAL SUSPENSION 250MG/5ML	5276/22T, 5277/22T, 5278/22T	020445	ELPEN PHARMACEUTICAL CO INC	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes
SITAGLIPTIN/MYLAN TABLET, FILM COATED 25MG	3449/22T	023446	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates

				to Mod. 3.2.S or the ASMF
SITAGLIPTIN/MYLAN TABLET, FILM COATED 25MG	3449/22T	023446	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SITAGLIPTIN/MYLAN TABLET, FILM COATED 100MG	3451/22T	023448	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SITAGLIPTIN/MYLAN TABLET, FILM COATED 100MG	3451/22T	023448	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	3450/22T	023447	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	3450/22T	023447	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
QUETRA TABLET, FILM COATED 1000MG	5351/22T	021011	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional

				data is required to be submitted by the MAH
QUETRA TABLET, FILM COATED 750MG	5352/22T	021010	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
QUETRA TABLET, FILM COATED 500MG	5353/22T	021009	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
QUETRA TABLET, FILM COATED 250MG	5354/22T	021008	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SITALOM TABLET, FILM COATED 15MG	7089/22T, 7090/22T, 7091/22T	021940	CODAL-SYNTO LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SITALOM TABLET, FILM COATED 10MG	7092/22T, 7093/22T, 7094/22T	021939	CODAL-SYNTO LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SITALOM TABLET, FILM COATED 20MG	7086/22T, 7087/22T, 7088/22T	021941	CODAL-SYNTO LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active

				substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SITALOM TABLET, FILM COATED 5MG	7095/22T, 7096/22T, 7097/22T	021938	CODAL-SYNTO LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
RISPERDAL TABLET, FILM COATED 2MG	3876/22T	014397	JANSSEN-CILAG INTERNATIONAL NV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
RISPERDAL TABLET, FILM COATED 4MG	3878/22T	014399	JANSSEN-CILAG INTERNATIONAL NV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
RISPERDAL ORAL SOLUTION 1MG/ML	3879/22T	017844	JANSSEN-CILAG INTERNATIONAL NV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
RISPERDAL TABLET, FILM COATED 3MG	3877/22T	014398	JANSSEN-CILAG INTERNATIONAL NV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
RISPERDAL TABLET, FILM COATED 1MG	3875/22T	014396	JANSSEN-CILAG INTERNATIONAL NV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ACTILYSE CATHFLO POWDER FOR SOLUTION FOR INJECTION/INFUSION 2MG	220/22T, 221/22T, 222/22T, 223/22T, 224/22T, 225/22T, 226/22T, 227/22T, 228/22T, 229/22T, 230/22T, 231/22T, 232/22T, 233/22T, 234/22T, 235/22T, 236/22T, 237/22T	023354	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture B.I.a.1.j B.I.a.1.j - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture B.I.a.1.k B.I.a.1.k - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture B.I.b.1.f B.I.b.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of a B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of a B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of activ B.I.e.2 B.I.e.2 - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Design Space and B.I.c.1.z B.I.c.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Container cl B.II.b.2.c.3 B.II.b.2.c.3 - QUALITY CHANGES - FINISHED PRODUCT - Manufa B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of
ACTILYSE POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1MG/ML	null	023353	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture B.I.a.1.j B.I.a.1.j - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture B.I.a.1.k B.I.a.1.k - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture B.I.b.1.f B.I.b.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Control of a B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of a B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of activ B.I.e.2 B.I.e.2 - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and B.I.c.1.z B.I.c.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Container cl B.II.b.2.c.3 B.II.b.2.c.3 - QUALITY CHANGES - FINISHED PRODUCT - Manufa B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of
VEDFA TABLET, FILM COATED 50MG/1000MG	6270/22T	023390	PHARMATHEN S.A.	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally

				approved batch size
VEDFA TABLET, FILM COATED 50MG/850MG	6271/22T	023389	PHARMATHEN S.A.	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size
MAYMETSI TABLET, FILM COATED 50MG/850MG	4315/22T	023374	TAD PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MAYMETSI TABLET, FILM COATED 50MG/1000MG	4316/22T	023375	TAD PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
IMATINIB/MYLAN TABLET, FILM COATED 400MG	5419/22T	023473	MYLAN PHARMACEUTICALS LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
IMATINIB/MYLAN TABLET, FILM COATED 100MG	5420/22T	023472	MYLAN PHARMACEUTICALS LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LIPTRUZET TABLET, FILM COATED 10MG/40MG	9470/21T	022098	N.V. ORGANON	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
LIPTRUZET TABLET, FILM COATED 10MG/20MG	9469/21T	022097	N.V. ORGANON	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
LIPTRUZET TABLET, FILM COATED 10MG/80MG	9471/21T	022099	N.V. ORGANON	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
LIPTRUZET TABLET, FILM COATED 10MG/10MG	9468/21T	022096	N.V. ORGANON	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT -

				Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	6124/22T	020206	GRIFOLS DEUTSCHLAND GMBH.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	6047/22T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated

				certificate from an already approved manufacturer
TAVANIC TABLET, FILM COATED 500MG	6003/22T	019283	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BEGALIN-P POWDER FOR SOLUTION FOR INJECTION (1G/2G)/VIAL	7186/22T	013278	PFIZER HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
VIDELMET TABLET, FILM COATED 50MG/850MG	5310/22T	023638	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
VIDELMET TABLET, FILM COATED 50MG/1000MG	5309/22T	023639	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
VIDELMET TABLET, FILM COATED 50MG/850MG	6594/22T	023638	DELORBIS PHARMACEUTICALS LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
VIDELMET TABLET, FILM COATED 50MG/1000MG	6593/22T	023639	DELORBIS PHARMACEUTICALS LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
LOSAR PLUS TABLET, FILM COATED 50MG/12.5MG	6341/22T	020782	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LOSAR PLUS TABLET, FILM COATED 50MG/12.5MG	6341/22T	020782	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LOSAR PLUS TABLET, FILM COATED 100MG/25MG	6342/22T	020783	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LOSAR PLUS TABLET, FILM COATED 100MG/25MG	6342/22T	020783	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PANTOPRAZOLE NORMON POWDER FOR SOLUTION FOR INJECTION 40MG/VIAL	3222/21T	022908	LABORATORIOS NORMON S.A	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the

				finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
CARDILOR TABLET 200MG	7141/22T	009126	REMEDICA LTD	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)
TRACRIUM INJECTION 10MG/ML	6143/22T	010430	ASPEN PHARMA TRADING LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
MAXIDEX EYE DROPS, SUSPENSION 0.1% W/V	4774/22T	017329	NOVARTIS IRELAND LIMITED	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
TOBREX EYE DROPS 0.3% W/V	4753/22T, 4754/22T, 4755/22T, 4756/22T, 4757/22T	017322	NOVARTIS IRELAND LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

				test procedure for the finished product - Minor changes to an approved test procedure B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
BINOSTO EFFERVESCENT TABLET 70MG	3376/22T	023029	GALENICA SA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 2MMOL/L	2046/22T, 2047/22T, 2048/22T	021044	BAXTER HOLDING B.V.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BIPHOZYL SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 22MMOL/L	2052/22T, 2053/22T, 2054/22T	022333	BAXTER HOLDING B.V.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 4MMOL/L	2043/22T, 2044/22T, 2045/22T	021045	BAXTER HOLDING B.V.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PHOXILIUM SOLUTION FOR HAEMOFILTRATION, HAEMODIAFILTRATION AND HAEMODIALYSIS	2049/22T, 2050/22T, 2051/22T	20655	BAXTER HOLDING B.V.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COSOPT IMULTI EYE DROPS, SOLUTION (20MG/5MG)/ML	9224/21T, 9225/21T	022891	VIANEX S.A	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	5946/22T	020206	GRIFOLS DEUTSCHLAND GMBH.	B.V.a.1.b B.V.a.1.b - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - First-time inclusion of a new Plasma Master File not affecting the properties of the finished product
SELGAMIS CREAM 50MCG/G	8308/21T, 8309/21T	023646	GALDERMA INTERNATIONAL,FRANCE	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
TRIVERAM TABLET, FILM COATED 20MG/10MG/10MG	6017/22T	022775	LES LABORATOIRES SERVIER	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TRIVERAM TABLET, FILM COATED 40MG/10MG/10MG	6018/22T	022776	LES LABORATOIRES SERVIER	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TRIVERAM TABLET, FILM COATED 20MG/10MG/5MG	6016/22T	022774	LES LABORATOIRES SERVIER	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TRIVERAM TABLET, FILM COATED 20MG/5MG/5MG	6015/22T	022773	LES LABORATOIRES SERVIER	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TRIVERAM TABLET, FILM COATED 10MG/5MG/5MG	6014/22T	022772	LES LABORATOIRES SERVIER	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SPORAL CAPSULE, HARD 100MG	5311/22T	012662	JANSSEN-CILAG INTERNATIONAL NV	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
SEIZAL TABLET, DISPERSIBLE 100MG	4413/22T, 4414/22T, 4415/22T	021701	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test

				B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product
SEIZAL TABLET, DISPERSIBLE 200MG	4416/22T, 4417/22T, 4418/22T	021702	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product
SEIZAL TABLET, DISPERSIBLE 50MG	4410/22T, 4411/22T, 4412/22T	021700	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.5.e B.II.b.5.e - QUALITY

				CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product
SEIZAL TABLET, DISPERSIBLE 5MG	4419/22T, 4420/22T, 4421/22T	021698	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product
SEIZAL TABLET, DISPERSIBLE 25MG	4407/22T, 4408/22T, 4409/22T	021699	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product
REMABIRAT TABLET, FILM COATED 1000MG	6674/22T	023507	REMEDICA LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
REMABIRAT TABLET, FILM COATED 500MG	6672/22T	023458	REMEDICA LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
REMABIRAT TABLET, FILM COATED 250MG	6673/22T	023457	REMEDICA LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
PARACETAMOL/BAXTER VIAFLO SOLUTION FOR INFUSION 10 MG/ML	3955/22T	023602	BAXTER HOLDING B.V.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product

				Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100/12.5MG	3558/22T	020921	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DALMEVIN TABLET 50MG	3379/21T	022644	MEDOCHEMIE LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of

				Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
DALMEVIN TABLET 50MG	2512/22T	022644	MEDOCHE MIE LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SOTALOL MC TABLET 80MG	5890/22T, 5891/22T	20645	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PROGRAF CAPSULE, HARD 0.5MG	4355/22T	022365	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
PROGRAF CAPSULE, HARD 1MG	4353/22T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
PROGRAF CAPSULE, HARD 5MG	4354/22T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
OXYNORM CONCENTRATE ORAL SOLUTION 10MG/ML	5398/21T	020973	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OXYNORM LIQUID ORAL SOLUTION 5MG/5ML	5397/21T	020972	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data
OXYNORM CAPSULE, HARD 20MG	5368/21T	020305	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OXYNORM CAPSULE, HARD 10MG	5367/21T	020306	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OXYNORM CAPSULE, HARD 5MG	5366/21T	020304	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OXYNORM SOLUTION FOR INJECTION OR INFUSION 50MG/ML	5458/21T	020595	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OXYNORM SOLUTION FOR INJECTION OR INFUSION 10MG/ML	5457/21T	020303	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
XYLOCREAM CREAM (2.5+2.5)% W/W	7054/22T	022729	VERISFIELD SINGLE MEMBER S.A.	B.II.f.1.a.1 B.II.f.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Reduction of the shelf life of the finished product - As packaged for sale
SPECENIB TABLET, FILM COATED 70MG	5973/22T, 5974/22T, 5975/22T, 5976/22T	023047	REMEDICA LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where

				specified in the technical doss B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
SPECENIB TABLET, FILM COATED 20MG	5981/22T, 5982/22T, 5983/22T, 5984/22T	023045	REMEDICA LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting

				material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
SPECENIB TABLET, FILM COATED 80MG	5969/22T, 5970/22T, 5971/22T, 5972/22T	023048	REMEDICA LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active

				substance, where no Ph. Eur. C B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
SPECENIB TABLET, FILM COATED 100MG	5965/22T, 5966/22T, 5967/22T, 5968/22T	023049	REMEDICA LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the

				active substance - Minor change to the restricted part of an Active Substance Master File
SPECENIB TABLET, FILM COATED 140MG	5961/22T, 5962/22T, 5963/22T, 5964/22T	023050	REMEDICA LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
SPECENIB TABLET, FILM COATED 50MG	5977/22T, 5978/22T, 5979/22T, 5980/22T	023046	REMEDICA LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a

				manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
FLUTICAPEN INHALATION POWDER, PRE-DISPENSED 500MCG/DOSE	6549/22T, 6550/22T, 6551/22T	020600	ELPEN PHARMACEUTICAL CO INC	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c -

				QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
FLUTICAPEN INHALATION POWDER, PRE-DISPENSED 250MCG/DOSE	6552/22T, 6553/22T, 6554/22T	020599	ELPEN PHARMACEUTICAL CO INC	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete

				parameter) B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
ASPRO CLEAR EFFERVESCENT TABLET 300MG	6625/22T, 6626/22T	022932	BAYER HELLAS ABEE	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
CARBOPLATIN/HOSPIRA SOLUTION FOR INFUSION 10MG/ML	6357/22T	012081	PFIZER HELLAS AE	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
NYSTALOCAL CREAM (100000U.I/1MG/11.5MG)/G	6446/22T	014149	A.D.L. PHARMACEUTICAL PRODUCTSLINE LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
IMATINIB TAD TABLET, FILM COATED 400MG	6517/22T	023684	TAD PHARMA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites

				for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
IMATINIB TAD TABLET, FILM COATED 100MG	6518/22T	023685	TAD PHARMA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CANESTEN CREAM 1%	7001/22T	004757	BAYER HELLAS ABEE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
BUSCOFEM EXTRA TABLET, FILM COATED 400MG/100MG	11107/20T	023552	SANOFI AVENTIS AEBE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BUSCOFEM EXTRA TABLET, FILM COATED 400MG/100MG	10609/20T	023552	SANOFI AVENTIS AEBE	A.2 b) for Nationally

				Authorised Products
BUSCOFEM EXTRA TABLET, FILM COATED 400MG/100MG	256/21T	023552	SANOFI AVENTIS AEBE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
BUSCOFEM EXTRA TABLET, FILM COATED 400MG/100MG	8658/20T	023552	SANOFI AVENTIS AEBE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
SPECENIB TABLET, FILM COATED 70MG	6926/22T	023047	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
SPECENIB TABLET, FILM COATED 80MG	6925/22T	023048	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension

				of the shelf life of the finished product - As packaged for sale (supported by real time data)
SPECENIB TABLET, FILM COATED 20MG	6928/22T	023045	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
SPECENIB TABLET, FILM COATED 140MG	6923/22T	023050	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
SPECENIB TABLET, FILM COATED 100MG	6924/22T	023049	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
SPECENIB TABLET, FILM COATED 50MG	6927/22T	023046	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for

				sale (supported by real time data)
MEDAXONUM POWDER FOR SOLUTION FOR INJECTION/INFUSION 2000MG/VIAL	6516/22T	020741	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MEDAXONUM POWDER FOR SOLUTION FOR INJECTION/INFUSION 250MG/VIAL	6515/22T	018562	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MEDAXONUM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	6514/22T	018563	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MEDAXONUM POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	6513/22T	018561	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RHESONATIV SOLUTION FOR INJECTION 625IU/ML	4130/22T, 4131/22T, 4132/22T	020158	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a

				medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	3808/22T, 3809/22T, 3810/22T, 3811/22T, 3812/22T	023308	OCTAPHARMA (IP) SPRL	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the ma B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tighte B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Additi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deleti

				B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (suc
LENALIDOMIDE STADA CAPSULE, HARD 25MG	6030/22T	023624	STADA ARZNEIMITTEL AG	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
LENALIDOMIDE STADA CAPSULE, HARD 15MG	6032/22T	023622	STADA ARZNEIMITTEL AG	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
LENALIDOMIDE STADA CAPSULE, HARD 20MG	6031/22T	023623	STADA ARZNEIMITTEL AG	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
LENALIDOMIDE STADA CAPSULE, HARD 7.5MG	6034/22T	023620	STADA ARZNEIMITTEL AG	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
LENALIDOMIDE STADA CAPSULE, HARD 10MG	6033/22T	023621	STADA ARZNEIMITTEL AG	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
LENALIDOMIDE STADA CAPSULE, HARD 2.5MG	6036/22T	023618	STADA ARZNEIMITTEL AG	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
LENALIDOMIDE STADA CAPSULE, HARD 5MG	6035/22T	023619	STADA ARZNEIMITTEL AG	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
MEROPENEM/KABI POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG	1891/22T	020996	FRESENIUS KABI HELLAS A.E.	B.II.f.1.b.3 B.II.f.1.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension

				of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)
MEROPENEM/KABI POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG	1892/22T	020997	FRESENIUS KABI HELLAS A.E.	B.II.f.1.b.3 B.II.f.1.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)
HYDROCORTISONE ACTIVASE TABLET 10MG	6046/22T	022648	ACTIVASE PHARMACEUTICALS LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
FOLIFER TABLET, FILM COATED	6353/22T	020218	BIAL-PORTELA & CA, SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
MOXICLAV BIS POWDER FOR ORAL SUSPENSION 457MG/5ML	6891/22T	021810	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
NOPRILAM 500 TABLET, FILM COATED (500MG/125MG)	6219/22T	018575	BIAL-PORTELA & CA, SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NOPRILAM 250 POWDER FOR ORAL SUSPENSION (250MG/62.5MG)/5ML	6221/22T	018574	BIAL-PORTELA & CA, SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	6222/22T	018573	BIAL-PORTELA & CA, SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NOPRILAM DT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	6220/22T	019090	BIAL-PORTELA & CA, SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NOPRILAM DT TABLET, FILM COATED 1000MG	6223/22T	018565	BIAL-PORTELA & CA, SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MOXICLAV TABLET, FILM COATED 375MG	6634/22T	016920	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal

				products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MOXICLAV TABLET, FILM COATED 625MG	6633/22T	016579	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MOXICLAV TABLET, FILM COATED 1G	null	019363	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to

				be submitted by the MAH
HUMULIN NPH SUSPENSION FOR INJECTION IN CARTRIDGE 100IU/ML	7927/21T	022894	PHADISCO LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change) C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
HUMULIN M3 SUSPENSION FOR INJECTION IN CARTRIDGE 100IU/ML	7926/21T	022895	PHADISCO LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan -

				Other RMP changes (e.g. agreed wording + template change) C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
HUMULIN REGULAR SOLUTION FOR INJECTION IN A CARTRIDGE 100IU/ML	7925/21T	022893	PHADISCO LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change) C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation,

				including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
WATER FOR INJECTION/CSL BEHRING SOLVENT FOR PARENTERAL USE	7897/21T, 7898/21T, 905/22T	022992	CSL BEHRING GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
EFAVIRENZ AUROBINDO TABLET, FILM COATED 600MG	1797/22T	022108	AUROBINDO PHARMA (MALTA) LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation
SALOFALK TABLET, GASTRO-RESISTANT 500MG	4899/22T	013056	DR. FALK PHARMA GMBH	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished

				product or the diluted/reconstituted product
TOBREX EYE OINTMENT 0.3% W/W	6937/22T	017321	NOVARTIS IRELAND LIMITED	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
DIENOGEST BESINS TABLET 2MG	3859/22T	023695	LABORATOIRES BESINS INTERNATIONAL	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
DIENOGEST BESINS TABLET 2MG	6793/22T	023695	LABORATOIRES BESINS INTERNATIONAL	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MEDOCEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	6257/22T	012622	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MEDOCEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G/VIAL	6256/22T	012621	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
METFORMIN ACCORD TABLET, FILM COATED 500MG	4604/22T	023548	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
METFORMIN ACCORD TABLET, FILM COATED 850MG	4603/22T	023549	ACCORD HEALTHCARE S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MAGNESIA S PELLEGRINO LEMON EFFERVESCENT POWDER 45%	5876/22T	016464	CEL CHADJIANASTASI PHARMACEUTICAL LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent

				authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
NETENAX EYE DROPS, SOLUTION 3MG/ML	318/22T	023364	NEWLINE PHARMA, S.L.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
NETENAX EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 3MG/ML	317/22T	023365	NEWLINE PHARMA, S.L.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
NETENAX EYE DROPS, SOLUTION 3MG/ML	9789/21T	023364	NEWLINE PHARMA, S.L.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NETENAX EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 3MG/ML	9788/21T	023365	NEWLINE PHARMA, S.L.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TOBRADEX EYE OINTMENT	6912/22T	017323	NOVARTIS IRELAND LIMITED	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when

				mentioned in the dossier) - Replacement or addition of a supplier
AMIKA-SYNTO SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	6190/22T	019842	CODAL-SYNTO LIMITED	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
AMIKA-SYNTO SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	6191/22T	019843	CODAL-SYNTO LIMITED	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
TOLTERANA PROLONGED RELEASE CAPSULES 4MG	5744/22T, 5745/22T, 5746/22T, 5747/22T, 5748/22T, 5749/22T, 5750/22T, 5751/22T, 5752/22T	021912	PHARMATHEN S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia
TOLTERANA PROLONGED RELEASE CAPSULES 2MG	5753/22T, 5754/22T, 5755/22T, 5756/22T, 5757/22T, 5758/22T, 5759/22T, 5760/22T, 5761/22T	021911	PHARMATHEN S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia
ZESTRIL TABLET 20MG	3649/22T, 3650/22T, 3651/22T, 3652/22T, 3653/22T, 3654/22T, 3655/22T	012876	ATNAHS PHARMA NETHERLANDS B.V.	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality cont B.II.b.3.a B.II.b.3.a

				- QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ B.II.b.4.b B.II.b.4.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finis B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletio
ZESTRIL TABLET 10MG	3642/22T, 3643/22T, 3644/22T, 3645/22T, 3646/22T, 3647/22T, 3648/22T	012875	ATNAHS PHARMA NETHERLANDS B.V.	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Change to importer, batch release arrangements and quality cont B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ B.II.b.4.b B.II.b.4.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finis B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletio
ZESTRIL TABLET 5MG	3635/22T, 3636/22T, 3637/22T, 3638/22T, 3639/22T, 3640/22T, 3641/22T	012874	ATNAHS PHARMA NETHERLANDS B.V.	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of B.II.b.2.c.2 B.II.b.2.c.2 -

				QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality cont B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ B.II.b.4.b B.II.b.4.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finis B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletio
ANDROXIL CUTANEOUS SOLUTION 2%	8070/21T, 8071/21T, 8072/21T, 8073/21T, 8074/21T, 8075/21T, 8076/21T, 8077/21T, 8078/21T, 8079/21T, 8080/21T, 8081/21T, 8082/21T	022100	LABORATOIRES BAILLEUL S.A	B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.1.a.2 B.II.e.1.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative

				composition - Semi-soli B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Additi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deleti
ANDROXIL CUTANEOUS SOLUTION 5%	8057/21T, 8058/21T, 8059/21T, 8060/21T, 8061/21T, 8062/21T, 8063/21T, 8064/21T, 8065/21T, 8066/21T, 8067/21T, 8068/21T, 8069/21T	022101	LABORATOIRES BAILLEUL S.A	B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.1.a.2 B.II.e.1.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate

				packaging of the finished product - Qualitative and quantitative composition - Semi-soli B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Additi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deleti
IMAREM TABLET, FILM COATED 100MG	4706/22T	021689	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the

				same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
IMAREM TABLET, FILM COATED 400MG	4705/22T	021690	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
AGGRASTAT CONCENTRATE FOR SOLUTION FOR INFUSION 0.25MG/ML	6877/22T	018260	CORREVIO	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in

				the technical dossier)
CANDIPLAS CREAM 2% W/W	6872/22T	019935	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DORZOTIM EYE DROPS, SOLUTION	5927/22T	021075	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
OCTISET CUTANEOUS SOLUTION	6783/22T, 6784/22T	022083	T.C.CHRISTOFOROU LTD.	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed

				manufacturer is part of the same pharmaceutical group as the currently approved manufacturer A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
OCTISET VAGINAL SOLUTION	6785/22T, 6786/22T	022084	T.C.CHRISTOFOROU LTD.	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the

				currently approved manufacturer A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
OLIMEL N7E EMULSION FOR INFUSION	2925/22T	022010	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL N9E EMULSION FOR INFUSION	2926/22T	022011	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL N12E EMULSION FOR INFUSION	2927/22T	023257	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL PERI N4E EMULSION FOR INFUSION	2924/22T	022008	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 10MG	4305/22T	018077	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 30MG	4303/22T	018079	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 20MG	4304/22T	018078	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 500MG/VIAL	4347/22T, 4348/22T	022843	SEACROSS PHARMA (EUROPE) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including

				batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/VIAL	4349/22T, 4350/22T	022842	SEACROSS PHARMA (EUROPE) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 40MG	294/22T	022171	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 20MG	295/22T	022170	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ABIRATERONE/PHARMAZAC TABLET, FILM COATED 500MG	3896/22T, 3897/22T	023488	PHARMAZAC S.A.	B.I.c.z B.I.c.z Change of a secondary packaging component of the drug substance (including replacement or addition) B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
ABIRATERONE/PHARMAZAC TABLET 250MG	3894/22T, 3895/22T	023487	PHARMAZAC S.A.	B.I.c.z B.I.c.z Change of a secondary packaging component of the drug substance (including replacement or addition) B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active

				substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
ABIRATERONE/PHARMAZAC TABLET 250MG	5093/22T	023487	PHARMAZAC S.A.	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
OXYNORM SOLUTION FOR INJECTION OR INFUSION 50MG/ML	2186/22T	020595	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
OXYNORM SOLUTION FOR INJECTION OR INFUSION 10MG/ML	2187/22T	020303	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
ALPRAZOLAM TAD TABLET 0.5MG	4040/22T	023244	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ALPRAZOLAM TAD TABLET 1MG	4041/22T	023245	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ALPRAZOLAM TAD TABLET 0.25MG	4039/22T	023243	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the

				same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LAMOSYNT TABLET 200MG	5995/22T	021490	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMOSYNT TABLET 25MG	5998/22T	021487	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate

				from an already approved manufacturer
LAMOSYNT TABLET 50MG	5997/22T	021488	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMOSYNT TABLET 100MG	5996/22T	021489	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MILOREX TABLET 5MG/50MG	5826/22T	010148	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PENEMNIA POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	929/22T	022318	PHARMATHEN S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PENEMNIA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	930/22T	022319	PHARMATHEN S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ASACOL SUPPOSITORY 500MG	5288/22T	019626	TILLOTTS PHARMA GMBH	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	4902/22T, 4903/22T, 4904/22T	022837	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

				Updated certificate from an already approved manufacturer
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	4905/22T, 4906/22T, 4907/22T	022213	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PACLITAXEL HOSPIRA CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	8337/21T, 8338/21T, 8339/21T, 8340/21T	016161	PFIZER HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
KRATIUM TABLET 5MG	6637/22T	019976	MEDOCHEMIE LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
DACARBAZINE LIPOMED POWDER FOR SOLUTION FOR INFUSION 1000MG/VIAL	9215/20T	022570	LIPOMED GMBH	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data

DACARBAZIN LIPOMED POWDER FOR SOLUTION FOR INJECTION/INFUSION 200MG/VIAL	9217/20T	021811	LIPOMED GMBH	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
DACARBAZINE LIPOMED POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	9216/20T	022569	LIPOMED GMBH	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
MYOVIEW KIT FOR RADIOPHARMACEUTICAL PREPARATION 0.23MG	7089/21T, 7090/21T, 7091/21T, 7092/21T	019632	GE HEALTHCARE AS (NYDALEN)	B.II.e.1.a.3 B.II.e.1.a.3 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or

				limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
ZOLARAM TABLET 1MG	5282/22T	014787	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
ZOLARAM TABLET 0.25MG	5281/22T	019739	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the

				specification with its corresponding test method
ZOLARAM TABLET 0.5MG	5280/22T	019740	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
ACTILYSE POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1MG/ML	5036/22T	023353	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ACTILYSE CATHFLO POWDER FOR SOLUTION FOR INJECTION/INFUSION 2MG	5035/22T	023354	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 4MMOL/L	null	021045	BAXTER HOLDING B.V.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 2MMOL/L	null	021044	BAXTER HOLDING B.V.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	5048/22T	023239	SANOFI PASTEUR.	B.I.a.5.a B.I.a.5.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes to the active substance of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza
HUMULIN M3 SUSPENSION FOR INJECTION IN CARTRIDGE 100IU/ML	7762/21T	022895	PHADISCO LTD	B.II.b.1.d B.II.b.1.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site which requires an initial or product specific inspection

ARCHIFAR POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	6628/22T	020810	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG	6629/22T	020809	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	5106/22T	null	ACCORD HEALTHCARE LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or

				change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	5105/22T	null	ACCORD HEALTHCARE LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
SYNTOPINE TABLET 200MG	4664/22T, 4665/22T, 4666/22T, 4667/22T, 4668/22T, 4669/22T, 4670/22T	020012	CODAL-SYNTO LIMITED	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
DYSPORT POWDER FOR SOLUTION FOR INJECTION 500U	6362/22T, 6363/22T, 6364/22T, 6365/22T, 6366/22T	019337	IPSEN M.E.P.E.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File w A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used

				in the manufacture of the active substance (where specified in the technical doss A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
VIDELMET TABLET, FILM COATED 50MG/1000MG	4424/22T, 4425/22T, 4426/22T, 4427/22T	023639	DELORBIS PHARMACEUTICALS LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the

				finished product - Site where any manufacturing operation(s) take place, ex B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
VIDELMET TABLET, FILM COATED 50MG/850MG	4428/22T, 4429/22T, 4430/22T, 4431/22T	023638	DELORBIS PHARMACEUTICALS LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing

				operation(s) take place, ex B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
FRISIUM TABLET 10MG	5289/22T	006698	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VIDEL TABLET 50MG	6595/22T	023400	DELORBIS PHARMACEUTICALS LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
DAPRIL TABLET 10MG	5283/22T	013084	MEDOCHEMIE LTD	B.II.a.z B.II.a.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Other variation

GLATIRAMER/MYLAN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	8033/21T, 8034/21T	023037	MYLAN IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
PULMOTON INHALATION POWDER, PRE-DISPENSED (200+6) MCG/DOSE	6543/22T, 6544/22T, 6545/22T	021865	ELPEN PHARMACEUTICAL CO INC	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED

				PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
PULMOTON INHALATION POWDER, PRE-DISPENSED (400+12) MCG/DOSE	6540/22T, 6541/22T, 6542/22T	021866	ELPEN PHARMACEUTICAL CO INC	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.z B.II.e.2.z - QUALITY

				CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
PULMOTON INHALATION POWDER, PRE-DISPENSED (100+6) MCG/DOSE	6546/22T, 6547/22T, 6548/22T	021864	ELPEN PHARMACEUTICAL CO INC	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
ASPENDOS TABLET 100MG	2238/22T	020929	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BENDAMUSTIN LEDPHARM POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 2.5MG/ML	3196/22T, 3197/22T	022423	O.S.K. LEDPHARM LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
CYCLOVAX TABLET 800MG	5261/22T	019882	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CYCLOVAX TABLET 400MG	5262/22T	014958	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CYCLOVAX CREAM 5% W/W	5260/22T	012652	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CYCLOVAX TABLET 200MG	5263/22T	012144	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SMOFKABIVEN EXTRA NITROGEN ELECTROLYTE FREE EMULSION FOR INFUSION	5083/21T	023283	FRESENIUS KABI HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
MANTOMED TABLET, FILM COATED 10MG	321/22T	022237	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation

MANTOMED TABLET, FILM COATED 5MG	323/22T	022236	MEDOCHE MIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM COATED 15MG	324/22T	022238	MEDOCHE MIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM COATED 20MG	322/22T	022239	MEDOCHE MIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (4G/0.5G)/VIAL	3821/22T, 3822/22T, 3823/22T, 3824/22T	020530	MYLAN IRELAND LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (2G/0.25G)/VIAL	3817/22T, 3818/22T, 3819/22T, 3820/22T	020529	MYLAN IRELAND LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size

				(including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 1000IU	3959/22T	022914	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	3958/22T	022913	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BILAZ TABLET, ORODISPERSIBLE 10MG	4988/22T	022833	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (4G/0.5G)/VIAL	4374/22T	020530	MYLAN IRELAND LIMITED	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (2G/0.25G)/VIAL	4375/22T	020529	MYLAN IRELAND LIMITED	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for

				the finished product - Minor changes to an approved test procedure
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 1000IU	5016/22T, 5017/22T	022914	OCTAPHARMA (IP) SPRL	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	5018/22T, 5019/22T	022913	OCTAPHARMA (IP) SPRL	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
SYNTOPAR TABLET 10MG	8264/20T	020195	CODAL SYNTO LTD	C.I.3 z) Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 Other variation
SYNTOPAR TABLET 40MG	8261/20T	020198	CODAL SYNTO LTD	C.I.3 z) Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 Other variation
SYNTOPAR TABLET 30MG	8262/20T	020197	CODAL SYNTO LTD	C.I.3 z) Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 Other variation
SYNTOPAR TABLET 20MG	8263/20T	020196	CODAL SYNTO LTD	C.I.3 z) Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 Other variation
SYNTOPAR TABLET 10MG	4326/20T	020195	CODAL SYNTO LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
SYNTOPAR TABLET 40MG	4323/20T	020198	CODAL SYNTO LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
SYNTOPAR TABLET 30MG	4324/20T	020197	CODAL SYNTO LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation

SYNTOPAR TABLET 20MG	4325/20T	020196	CODAL SYNTO LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
SYNTOPAR TABLET 10MG	716/21T	020195	CODAL SYNTO LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SYNTOPAR TABLET 40MG	719/21T	020198	CODAL SYNTO LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SYNTOPAR TABLET 30MG	718/21T	020197	CODAL SYNTO LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SYNTOPAR TABLET 20MG	717/21T	020196	CODAL SYNTO LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
CASPOFUNGIN DEMO POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 70MG/VIAL	4868/22T	022519	DEMO S.A.	B.I.z B.I.z - Quality change - Active substance - Other variation
CASPOFUNGIN DEMO POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 50MG/VIAL	4869/22T	022518	DEMO S.A.	B.I.z B.I.z - Quality change - Active substance - Other variation
DIENOGEST BESINS TABLET 2MG	3202/22T	023695	LABORATOIRES BESINS INTERNATIONAL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
UTROGESTAN CAPSULE, SOFT 200MG	6171/22T	023191	BESINS HEALTHCARE IRELAND LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
UTROGESTAN CAPSULE, SOFT 100MG	6172/22T	013736	BESINS HEALTHCARE IRELAND LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PIRAZOL TABLET 10MG	5303/22T	022878	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PIRAZOL TABLET 5MG	5304/22T	022877	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

PIRAZOL TABLET 30MG	5305/22T	022881	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PIRAZOL TABLET 20MG	5301/22T	022880	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PIRAZOL TABLET 15MG	5302/22T	022879	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
GRABILEN CAPSULE, HARD 75MG	6021/22T	023038	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GRABILEN CAPSULE, HARD 150MG	6020/22T	023039	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GRABILEN CAPSULE, HARD 300MG	6019/22T	023040	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VISPRING ADVANCE EYE DROPS, SOLUTION 0.5MG/ML	3708/22T	023286	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
VEREGREEN OINTMENT 10%	3816/22T	021499	MEDITRINA PHARMACEUTICALS LTD	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test

				period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
VEREGREEN OINTMENT 10%	4578/22T	021499	MEDITRINA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BETAISODONA VAGINAL DOUCHE 10% W/V	4451/22T	019867	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA SCALP & SKIN CLEANSER SOLUTION 7.5% W/V	4459/22T	012330	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA SURGICAL SCRUB 7.5% W/V	4452/22T	019861	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA VAGINAL GEL 10% W/W	4460/22T	012884	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA THROAT SPRAY OROMUCOSAL SPRAY 0.45% W/V	4456/22T	018736	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA GARGLE/MOUTHWASH 1% W/V	4454/22T	012423	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet

				due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA SKIN CLEANSER CUTANEOUS SOLUTION 4% W/V	4455/22T	013786	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA OINTMENT 10% W/W	4463/22T	019996	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA VAGINAL SUPPOSITORIES 200MG	4464/22T	019994	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA STANDARDISED SOLUTION 10% W/V	4453/22T	019992	MUNDIPHARMA	C.I.4 C.I.4 - SAFETY, EFFICACY,

			PHARMACEUTICALS LTD	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA ANTISEPTIC PAINT SOLUTION 10% W/V	4462/22T	019864	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA ALCOHOLIC CUTANEOUS SOLUTION 10% W/V	4457/22T	019993	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA DRY POWDER, CUTANEOUS SPRAY 2.5% W/W	4458/22T	019817	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BETAISODONA CREAM 5% W/W	null	014789	MUNDIPHARMA	C.I.4 C.I.4 - SAFETY,

			PHARMACEUTICALS LTD	EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	4309/22T	020206	GRIFOLS DEUTSCHLAND GMBH.	B.II.e.4.b B.II.e.4.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - The change in shape or dimensions concerns a fundamental part of the packaging material, which may have a significant impact on the delivery, use, safety or stability of the finished product
DETRUSITOL TABLET, FILM COATED 2MG	5076/22T	023122	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NORVASC CAPSULE, HARD 10MG	5089/22T	013775	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NORVASC CAPSULE, HARD 5MG	5090/22T	013774	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

MELPHALAN TILLOMED POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 50MG/VIAL	5991/22T, 5992/22T, 5993/22T, 5994/22T	022629	TILLOMED PHARMA GMBH.	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.f.1.e B.II.f.1.e - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change to an approved stability protocol B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits
AUDAX EAR DROPS 20% W/V	4441/22T	020337	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical

				or pharmacovigilance data
MUNDISAL GEL ORAL GEL 8.71% W/W	4440/22T	019997	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
RYCARDON TABLET, FILM COATED 150MG	6254/22T	020739	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RYCARDON TABLET, FILM COATED 300MG	6253/22T	020740	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a

				generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
METHOTREXATE/PFIZER TABLET 2.5MG	735/22T	002904	PFIZER HELLAS AE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
METHOTREXATE SOLUTION FOR INJECTION 25MG/ML	736/22T	012084	PHARMACEUTICAL TRADING CO LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended

				to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
LIVIAL TABLET 2.5MG	593/21T	013428	N.V. ORGANON	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
URSOFALK CAPSULE, HARD 250MG	6313/22T, 6314/22T, 6315/22T	009649	DR. FALK PHARMA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.III.1.a.4 B.III.1.a.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
NIZORAL SHAMPOO 20MG/G	6286/22T	012220	STADA ARZNEIMITTEL AG	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Updated certificate from an already approved manufacturer
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 200MG	3275/22T	021233	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY

				CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 300MG	3276/22T	021234	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 150MG	3278/22T	022451	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
QUETIAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	3277/22T	021235	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 200IU/ML(1000IU/5ML)	3343/22T	023296	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 100IU/ML(500IU/5ML)	3342/22T	023295	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000 (100 IU/ml)	3341/22T	020062	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250/500 (50 IU/ml)	3340/22T	020061	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PRAGIOLA CAPSULE, HARD 75MG	3380/22T, 3381/22T	022689	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following

				assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
PRAGIOLA CAPSULE, HARD 150MG	3382/22T, 3383/22T	022690	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional

				data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
PRAGIOLA CAPSULE, HARD 300MG	3384/22T, 3385/22T	022691	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
PRAGIOLA CAPSULE, HARD 25MG	3378/22T, 3379/22T	022688	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or

				package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
MAVIXAN TABLET 5MG	6041/22T	021313	PHARMATHEN S.A.	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
MAVIXAN TABLET 10MG	6040/22T	021314	PHARMATHEN S.A.	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
MAVIXAN TABLET, ORODISPERSIBLE 10MG	6038/22T	021312	PHARMATHEN S.A.	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product -

				Secondary packaging site
MAVIXAN TABLET, ORODISPERSIBLE 5MG	6039/22T	021311	PHARMATHEN S.A.	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	5580/22T	022925	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 200IU/ML(1000IU/5ML)	3727/22T, 3728/22T, 3729/22T, 3730/22T, 3731/22T	023296	OCTAPHARMA (IP) SPRL	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.b B.II.e.2.b - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specifi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 100IU/ML(500IU/5ML)	3722/22T, 3723/22T, 3724/22T, 3725/22T, 3726/22T	023295	OCTAPHARMA (IP) SPRL	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.b B.II.e.2.b - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specifi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250/500 (50 IU/ml)	3712/22T, 3713/22T, 3714/22T, 3715/22T, 3716/22T	020061	OCTAPHARMA (IP) SPRL	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.b B.II.e.2.b - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specifi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000 (100 IU/ml)	3717/22T, 3718/22T, 3719/22T, 3720/22T, 3721/22T	020062	OCTAPHARMA (IP) SPRL	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.b B.II.e.2.b - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specifi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal produ
PAMECIL POWDER FOR SOLUTION FOR INJECTION 1G/VIAL	4914/22T, 4915/22T, 4916/22T	012623	MEDOCHE MIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process

				B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PAMECIL POWDER FOR SOLUTION FOR INJECTION 500MG/VIAL	4911/22T, 4912/22T, 4913/22T	012437	MEDOCHE MIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PAMECIL POWDER FOR SOLUTION FOR INJECTION 250MG	4908/22T, 4909/22T, 4910/22T	012770	MEDOCHE MIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished

				product - Change in test procedure for the finished product - Minor changes to an approved test procedure
BELARMIN SYRUP 14MG/5ML	4709/22T, 4710/22T	007739	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
VOLTAREN D TABLET, DISPERSIBLE 50MG	6029/22T	018457	NOVARTIS IRELAND LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
NEXIUM TABLET, GASTRO-RESISTANT 40MG	2835/21T	019421	C G PAPALOISOU LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data
NEXIUM I.V. POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG	2836/21T	019788	C G PAPALOISO U LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
NEXIUM TABLET, GASTRO-RESISTANT 20MG	2834/21T	019420	C G PAPALOISO U LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
NEXIUM GASTRO-RESISTANT GRANULES FOR ORAL SUSPENSION 10MG	2833/21T	020461	C G PAPALOISO U LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
PRAGIOLA CAPSULE, HARD 75MG	5012/22T	022689	KRKA D.D. NOVO MESTO	A.z A.z - ADMINISTRATIVE CHANGES - Other variation

PRAGIOLA CAPSULE, HARD 150MG	5011/22T	022690	KRKA D.D. NOVO MESTO	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PRAGIOLA CAPSULE, HARD 300MG	5010/22T	022691	KRKA D.D. NOVO MESTO	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PRAGIOLA CAPSULE, HARD 25MG	5013/22T	022688	KRKA D.D. NOVO MESTO	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TICAGRELOR/MYLAN TABLET, FILM COATED 90MG	4972/22T	023358	MYLAN IRELAND LIMITED	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
TICAGRELOR/MYLAN TABLET, FILM COATED 60MG	4973/22T	023357	MYLAN IRELAND LIMITED	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
PRAGIOLA CAPSULE, HARD 75MG	1294/22T, 1295/22T	022689	KRKA D.D. NOVO MESTO	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for

				batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
PRAGIOLA CAPSULE, HARD 150MG	1296/22T, 1297/22T	022690	KRKA D.D. NOVO MESTO	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
PRAGIOLA CAPSULE, HARD 300MG	1298/22T, 1299/22T	022691	KRKA D.D. NOVO MESTO	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer

				(replacement or addition)
PRAGIOLA CAPSULE, HARD 25MG	1292/22T, 1293/22T	022688	KRKA D.D. NOVO MESTO	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
AMOXAPEN TABLET, DISPERSIBLE 250MG	3615/22T	022764	REMEDICA LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TOBRADEX EYE DROPS, SUSPENSION 0,1% w/v + 0,3% w/v	6181/22T	017319	NOVARTIS IRELAND LIMITED	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
CANDIPLAS CREAM 2% W/W	5258/22T	019935	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TOBRADEX EYE OINTMENT	6096/22T	017323	NOVARTIS IRELAND LIMITED	B.III.2.b B.III.2.b - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
IMATINIB/MYLAN TABLET, FILM COATED 100MG	10986/20T	023472	MYLAN PHARMACEUTICALS LIMITED	A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
IMATINIB/MYLAN TABLET, FILM COATED 400MG	10985/20T	023473	MYLAN PHARMACEUTICALS LIMITED	A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DEPAKINE CHRONO TABLET, PROLONGED-RELEASE 500MG	7289/21T	019172	SANOFI-AVENTIS GROUPE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data

IMATINIB/MYLAN TABLET, FILM COATED 100MG	2884/21T	023472	MYLAN PHARMACEUTICALS LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
IMATINIB/MYLAN TABLET, FILM COATED 400MG	2885/21T	023473	MYLAN PHARMACEUTICALS LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 500MG/VIAL	319/22T	022843	SEACROSS PHARMA (EUROPE) LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally

				Authorised Products
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/VIAL	320/22T	022842	SEACROSS PHARMA (EUROPE) LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ALSAMOD TABLET, FILM COATED 40MG/5MG	5769/22T	023344	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
ALSAMOD TABLET, FILM COATED 40MG/10MG	5770/22T	023345	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under

				Articles 45 or 46 of Regulation 1901/2006 - Other variation
ALSAMOD TABLET, FILM COATED 20MG/5MG	5771/22T	023343	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
OCTISET CUTANEOUS SOLUTION	6620/21T, 6621/21T	022083	T.C.CHRISTOFOROU LTD.	B.II.e.1.a.2 B.II.e.1.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products

AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 5/160/12.5MG	3834/22T	023475	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/320/25MG	3838/22T	023479	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/160/25MG	3837/22T	023478	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 5/160/25MG	3835/22T	023476	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/160/12.5MG	3836/22T	023477	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	5051/22T	020984	SANDOZ GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	5050/22T	020985	SANDOZ GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting

				material/intermediate
ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	5049/22T	020987	SANDOZ GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
PANADOL COLD & FLU & COUGH CAPSULE, HARD 500MG/100MG/6.1MG	4277/22T, 4278/22T	022695	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
SEVELAMER LEDPHARM TABLET, FILM COATED 800MG	5612/21T	022733	O.S.K. LEDPHARM LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
AUGMENTIN MIXED FRUIT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	3797/21T, 3798/21T	022824	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority, e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Impleme C.I.z C.I.z -

				SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
AUGMENTIN POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	null	019702	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority, e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Impleme C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CLOPIDOGREL ACCORD TABLET, FILM COATED 75MG	5649/22T, 5650/22T	021757	ACCORD HEALTHCARE S.L.U	B.II.b.1.a B.II.b.1.a - QUALITY

				CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
REXANIB TABLET, FILM COATED 400MG	4807/22T	023438	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
REXANIB TABLET, FILM COATED 200MG	4808/22T	023207	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TRISEQUENS TABLET, FILM COATED	4681/22T	013501	NOVO NORDISK HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a

				recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority.
BICALUTAMIDE ACCORD TABLET, FILM COATED 50MG	3318/22T	020794	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
SPIRIVA INHALATION POWDER, HARD CAPSULE 18MCG	1740/22T, 1741/22T, 1742/22T, 1743/22T, 1744/22T	021138	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.b B.II.d.2.b - QUALITY

				CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes
BICALUTAMIDE ACCORD TABLET, FILM COATED 50MG	5015/22T	020794	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
OMNIC TOCAS TABLET, PROLONGED-RELEASE 0.4MG	5828/22T	022184	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur.

				Monograph - Updated certificate from an already approved manufacturer
OMNIC MODIFIED-RELEASE CAPSULE, HARD 0.4MG	5827/22T	022169	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LOGIMAX TABLET, PROLONGED-RELEASE 5MG/50MG	4749/22T, 4750/22T, 4751/22T, 4752/22T	016252	RECORDATI IRELAND LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.1

				B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
ACLONIA TABLET 70MG/5600IU	5101/22T, 5102/22T	022675	PHARMATHEN S.A.	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change in the specification parameters and/or limits of the finished product to more accurately describe the appearance of the drug product B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ACLONIA TABLET 70MG/2800IU	5099/22T, 5100/22T	022674	PHARMATHEN S.A.	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change in the specification parameters and/or limits of the finished product to more accurately describe the appearance of the drug product B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	4998/22T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.5.a B.I.a.5.a - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Manufacture - Changes to the active substance of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza
AMARYL TABLET 1MG	2870/22T	020550	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 4MG	2873/22T	20553	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 3MG	2872/22T	20552	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 2MG	2871/22T	20551	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEBIDO SOLUTION FOR INJECTION 1000MG/4ML	2593/22T	019681	BAYER HELLAS ABEE	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
LUCIDEL PLUS TABLET, FILM COATED (300+12.5)MG	4955/22T, 4956/22T, 4957/22T	022180	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LUCIDEL PLUS TABLET, FILM COATED (300+25)MG	4952/22T, 4953/22T, 4954/22T	022181	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LUCIDEL PLUS TABLET, FILM COATED (150+12.5)MG	4958/22T, 4959/22T, 4960/22T	022179	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LUCIDEL PLUS TABLET, FILM COATED (300+12.5)MG	4762/20T, 4763/20T	022180	ELPEN PHARMACEUTICAL CO INC	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
LUCIDEL PLUS TABLET, FILM COATED (300+25)MG	4760/20T, 4761/20T	022181	ELPEN PHARMACEU	C.I.2 a) Implementation of

			TICAL CO INC	change(s) for which no new additional data is required to be submitted by the MAH C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
LUCIDEL PLUS TABLET, FILM COATED (150+12.5)MG	4764/20T, 4765/20T	022179	ELPEN PHARMACEUTICAL CO INC	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	8887/21T	023149	ACCORD HEALTHCARE S.L.U	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	8888/21T	023150	ACCORD HEALTHCARE S.L.U	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	8889/21T	023151	ACCORD HEALTHCARE S.L.U	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active

				substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	8886/21T	023148	ACCORD HEALTHCARE S.L.U	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 40MG	1886/22T	null	SANDOZ GMBH	B.II.e.3.a B.II.e.3.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure
ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 20MG	1885/22T	null	SANDOZ GMBH	B.II.e.3.a B.II.e.3.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure
ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 10MG	1884/22T	null	SANDOZ GMBH	B.II.e.3.a B.II.e.3.a - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure
ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 5MG	1883/22T	null	SANDOZ GMBH	B.II.e.3.a B.II.e.3.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure
COMPRELAN TABLET, FILM COATED 40MG/10MG	3239/22T, 3240/22T	023570	RAFARM S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COMPRELAN TABLET, FILM COATED 40MG/5MG	3237/22T, 3238/22T	023569	RAFARM S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
COMPRELAN TABLET, FILM COATED 20MG/5MG	3235/22T, 3236/22T	023568	RAFARM S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)

VILDAGLIPTIN ACCORD TABLET 50MG	4336/22T	023190	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
VILDAGLIPTIN ACCORD TABLET 50MG	1282/22T	023190	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
COMPRELAN TABLET, FILM COATED 40MG/5MG	5187/22T	023569	RAFARM S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the

				assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
COMPRELAN TABLET, FILM COATED 40MG/10MG	5189/22T	023570	RAFARM S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
COMPRELAN TABLET, FILM COATED 20MG/5MG	5188/22T	023568	RAFARM S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent

				authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
APIXABAN/MYLAN TABLET, FILM COATED 5MG	3217/22T	023470	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
APIXABAN/MYLAN TABLET, FILM COATED 2.5MG	3218/22T	023469	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of

				Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FLUOROURACIL ACCORD SOLUTION FOR INJECTION OR INFUSION 50MG/ML	9800/21T	021926	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TADALAFIL ACCORD TABLET, FILM COATED 5MG	9114/21T	022693	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

TADALAFIL ACCORD TABLET, FILM COATED 20MG	9115/21T	022571	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
CONCERTA TABLET, PROLONGED-RELEASE 54MG	3147/22T	020336	JANSSEN-CILAG INTERNATIONAL NV	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONCERTA TABLET, PROLONGED-RELEASE 36MG	3146/22T	020340	JANSSEN-CILAG INTERNATIONAL NV	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONCERTA TABLET, PROLONGED-RELEASE 18MG	3145/22T	020339	JANSSEN-CILAG INTERNATIONAL NV	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ATORVASTATIN UPJOHN TABLET, FILM COATED 40MG	3148/22T	021891	UPJOHN HELLAS LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
ATORVASTATIN UPJOHN TABLET, FILM COATED 80MG	3149/22T	021892	UPJOHN HELLAS LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient

LIPITOR TABLET, FILM COATED 40MG	3151/22T	019491	UPJOHN HELLAS LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
LIPITOR TABLET, FILM COATED 20MG	3150/22T	019490	UPJOHN HELLAS LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
LIPITOR TABLET, FILM COATED 10MG	3152/22T	019489	UPJOHN HELLAS LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
TENORMIN TABLET, FILM COATED 25MG	2232/22T	014974	ATNAHS PHARMA NETHERLANDS B.V.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TENORMIN TABLET, FILM COATED 100MG	2234/22T	010559	ATNAHS PHARMA NETHERLANDS B.V.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TENORMIN TABLET, FILM COATED 50MG	2233/22T	010558	ATNAHS PHARMA NETHERLANDS B.V.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TENORETIC TABLET, FILM COATED 100MG/25MG	2235/22T	010556	ATNAHS PHARMA NETHERLANDS B.V.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LIPOCOMB CAPSULE, HARD 20MG/10MG	5809/22T	023609	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance -

			GYÓGYSZER GYÁR ZRT)	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
LIPOCOMB CAPSULE, HARD 10MG/10MG	5810/22T	023608	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
NIZORAL SHAMPOO 20MG/G	3162/22T	012220	STADA ARZNEIMITTEL AG	B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an

				active substance/starting material/reagent/ intermediate/or excipient - New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	2390/22T	022925	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
PARACETAMOL/KABI SOLUTION FOR INFUSION 10MG/ML	694/22T	022781	FRESENIUS KABI HELLAS A.E.	B.II.e.1.b.2 B.II.e.1.b.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/ immunological medicinal products
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	3179/22T	023276	MYLAN IRE HEALTHCARE LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	3178/22T	023275	MYLAN IRE HEALTHCARE LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BINOSTO EFFERVESCENT TABLET 70MG	3072/22T	023029	GALENICA SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
AMBRISENTAN ACCORD TABLET, FILM COATED 5MG	5159/22T	023248	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AMBRISENTAN ACCORD TABLET, FILM COATED 10MG	5158/22T	023249	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TOSTRAN GEL 2%	6179/21T, 6180/21T, 6181/21T, 6182/21T, 6183/21T, 6184/21T	022871	KYOWA KIRIN HOLDINGS B.V.	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PANTOFLUX TABLET, GASTRO-RESISTANT 20MG	3881/22T	022045	ACTAVIS GROUP PTC EHF	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PANTOFLUX TABLET, GASTRO-RESISTANT 40MG	3882/22T	022046	ACTAVIS GROUP PTC EHF	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LACTULOSE RESOLUTION ORAL SOLUTION 3.3G/5ML	3919/22T	020705	RELAX LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LAMISIL TABLET 125MG	4656/22T, 4657/22T	018387	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
EMCONCOR TABLET, FILM COATED 5MG	2934/20T	022173	MERCK A E HELLAS	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
EMCONCOR TABLET, FILM COATED 2.5MG	2935/20T	022172	MERCK A E HELLAS	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
CONCOR TABLET, FILM COATED 10MG	4351/20T	021708	MERCK A E HELLAS	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
CONCOR TABLET, FILM COATED 5MG	4352/20T	012863	MERCK A E HELLAS	C.I.4 Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
SYNTOSARTIN TABLET 300MG	3983/22T, 3984/22T	020977	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SYNTOSARTIN TABLET 150MG	3981/22T, 3982/22T	020976	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SYNTOSARTIN TABLET 75MG	3979/22T, 3980/22T	020975	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the

				relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LAMISIL TABLET 250MG	4655/22T	018385	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
CONCOR TABLET, FILM COATED 10MG	5695/21T, 5696/21T	021708	MERCK A E HELLAS	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or

				finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CONCOR TABLET, FILM COATED 5MG	5693/21T, 5694/21T	012863	MERCK A E HELLAS	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NIFELAT R MODIFIED-RELEASE TABLET 20MG	571/22T, 572/22T, 573/22T, 574/22T, 575/22T	012109	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1

				- QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w
NIFELAT TABLET, FILM COATED 10MG	576/22T, 577/22T, 578/22T, 579/22T, 580/22T	019905	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w
VOLTAREN RETARD SUSTAINED RELEASE TABLETS 100MG	5292/22T, 5293/22T	018444	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in

				the technical dossier) B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
VOLTAREN TABLET, GASTRO-RESISTANT 50MG	5290/22T, 5291/22T	018455	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or

				limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
VOLTAREN SR SUSTAINED RELEASE TABLETS 75MG	5294/22T, 5295/22T	018459	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g.

				deletion of an obsolete parameter)
DERMOVATE CREAM 0.05% W/W	5636/22T	016801	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
IMIGRAN TABLET, FILM COATED 50MG	5637/22T	019508	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
DERMOVATE OINTMENT 0.05% W/W	5635/22T	016802	GLAXOSMITHKLINE (IRELAND) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
LIPREN TABLET, FILM COATED 40MG	5836/22T	022168	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LIPREN TABLET, FILM COATED 10MG	5838/22T	022166	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LIPREN TABLET, FILM COATED 20MG	5837/22T	022167	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
DORZON EYE DROPS, SOLUTION 2%	5928/22T	020543	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ONCOTICE POWDER FOR SOLUTION FOR INFUSION	4698/22T	019017	MSD AFVEE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GLUCOPHAGE TABLET, FILM COATED 850MG	2465/22T, 2466/22T	020698	MERCK A E HELLAS	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GLUCOPHAGE TABLET, FILM COATED 500MG	2463/22T, 2464/22T	020697	MERCK A E HELLAS	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GLUCOPHAGE TABLET, FILM COATED 1000MG	2467/22T, 2468/22T	020469	MERCK A E HELLAS	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

MAINTELYTE SOLUTION FOR INFUSION 50G/L	2588/22T, 2589/22T, 2590/22T, 2591/22T	023215	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 2MG	8372/21T	022006	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
ATORVASTATIN ACCORD TABLET, FILM COATED 20MG	1801/22T	022738	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following

				assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ATORVASTATIN ACCORD TABLET, FILM COATED 10MG	1800/22T	022737	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ATORVASTATIN ACCORD TABLET, FILM COATED 40MG	1802/22T	022739	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
XEOMIN POWDER FOR SOLUTION FOR INJECTION 200 UNITS	3089/22T	022628	MERZ PHARMACEUTICALS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	3088/22T	022002	MERZ PHARMACEUTICALS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures -

				PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	3087/22T	022001	MERZ PHARMACEUTICALS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 100U	3091/22T	023324	MERZ PHARMACEUTICALS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an

				updated/amended Plasma Master File when changes do not affect the properties of the finished product
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 50U	3090/22T	023325	MERZ PHARMACEUTICALS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
SUNITINIB SANDOZ CAPSULE, HARD 50MG	3312/22T	null	SANDOZ GMBH	B.I.z B.I.z - Quality change - Active substance - Other variation
SUNITINIB SANDOZ CAPSULE, HARD 37.5MG	3313/22T	null	SANDOZ GMBH	B.I.z B.I.z - Quality change - Active substance - Other variation
SUNITINIB SANDOZ CAPSULE, HARD 25MG	3311/22T	null	SANDOZ GMBH	B.I.z B.I.z - Quality change - Active substance - Other variation
SUNITINIB SANDOZ CAPSULE, HARD 12.5MG	3310/22T	null	SANDOZ GMBH	B.I.z B.I.z - Quality change - Active substance - Other variation
SALOFALK SUPPOSITORY 500MG	7423/21T	013057	DR. FALK PHARMA GMBH	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or

				batch release - Not including batch control/testing
SALOFALK ENEMA 4G/60ML	7424/21T	012246	DR. FALK PHARMA GMBH	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
MUCOFALK ORANGE GRANULES FOR ORAL SUSPENSION 3.25G/5G SACHET	3750/21T, 3751/21T, 3752/21T, 3753/21T, 3754/21T, 3755/21T, 3756/21T, 3757/21T, 3758/21T, 3759/21T, 3760/21T, 3761/21T, 3762/21T, 3763/21T, 3764/21T, 3765/21T, 3766/21T	007597	DR. FALK PHARMA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition B.II.e.7.a B.II.e.7.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Change in the name of a B.II.e.2.c B.II.e.2.c - QUALITY

				CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deleti B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Additi
LIPIDIL NT TABLET, FILM COATED 145MG	4894/22T	021153	MYLAN IRE HEALTHCARE LIMITED	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
ADRENALINE INJECTION 1MG/ML	4489/22T, 4490/22T	019818	NORIDEM ENTERPRISES LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
TRINISTEM TABLET, FILM COATED 600MG/200MG/245MG	5312/22T	022699	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of

				wording agreed by the competent authority
TRILEPTAL TABLET, FILM COATED 150MG	5719/22T	019109	NOVARTIS IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TRILEPTAL TABLET, FILM COATED 300MG	5718/22T	018463	NOVARTIS IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
TRILEPTAL TABLET, FILM COATED 600MG	5717/22T	018464	NOVARTIS IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TRILEPTAL ORAL SUSPENSION 60MG/ML	5716/22T	019494	NOVARTIS IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

VENLAXIN TABLET, PROLONGED-RELEASE 75MG	5859/22T	021935	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
VENLAXIN TABLET, PROLONGED-RELEASE 225MG	5857/22T	021937	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
VENLAXIN TABLET, PROLONGED-RELEASE 150MG	5858/22T	021936	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
REFENTA POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION 2MG	5608/22T, 5609/22T	022215	SAPIENS PHARMACEUTICALS LTD	B.II.g.5.a B.II.g.5.a - QUALITY CHANGES - FINISHED PRODUCT - Design Space and post approval change management protocol - Implementation of changes foreseen in an approved

				change management protocol - The implementation of the change requires no further supportive data
REMETHAN TABLET, GASTRO-RESISTANT 50MG	5942/22T	019633	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
REMETHAN TABLET, PROLONGED-RELEASE 100MG	5944/22T	012480	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
REMETHAN TABLET, GASTRO-RESISTANT 25MG	5943/22T	010334	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZYKALOR TABLET 15MG	1158/22T	022283	MEDOCHEMIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ZYKALOR TABLET 30MG	1160/22T	022285	MEDOCHEMIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ZYKALOR TABLET 5MG	1156/22T	022281	MEDOCHEMIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ZYKALOR TABLET 20MG	1159/22T	022284	MEDOCHE MIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ZYKALOR TABLET 10MG	1157/22T	022282	MEDOCHE MIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
TADALAFIL ACCORD TABLET, FILM COATED 5MG	315/22T	022693	ACCORD HEALTHCAR E S.L.U	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
PARACETAMOL/BAXTER SOLUTION FOR INFUSION 10MG/ML	3940/22T	023567	BAXTER HOLDING B.V.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product

				Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/VIAL	8117/21T	022438	IBSA FARMACEUTICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/VIAL	8116/21T	022437	IBSA FARMACEUTICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML PFS	8115/21T	022176	IBSA FARMACEUTICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML PFS	8114/21T	022175	IBSA FARMACEUTICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT -

				Control of excipients - Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	3108/22T	20630	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUREX 5 SOLUTION FOR INFUSION 50G/L	3107/22T	20629	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
MERIOFERT POWDER AND SOLVENT FOR	8509/21T	022438	IBSA FARMACEUT	A.1 A.1 - ADMINISTRATIVE

SOLUTION FOR INJECTION 150IU/VIAL			ICI ITALIA SRL	CHANGES - Change in the name and/or address of the marketing authorisation holder
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/VIAL	8508/21T	022437	IBSA FARMACEUTICI ITALIA SRL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML PFS	8507/21T	022176	IBSA FARMACEUTICI ITALIA SRL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML PFS	8506/21T	022175	IBSA FARMACEUTICI ITALIA SRL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CANESTEN VAGINAL TABLET 500MG	5845/22T	023091	BAYER HELLAS ABEE	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
ISOPTO-MAXITROL EYE OINTMENT	5253/22T	017327	NOVARTIS IRELAND LIMITED	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 750MG	5242/22T	022948	MERCK A E HELLAS	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of

				manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 1000MG	5241/22T	022949	MERCK A E HELLAS	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 500MG	5243/22T	022947	MERCK A E HELLAS	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MECOLZINE TABLET, GASTRO-RESISTANT 1000MG	5067/22T	023468	FAES FARMA SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MECOLZINE TABLET, GASTRO-RESISTANT 500MG	5066/22T	023332	FAES FARMA SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PROLUTEX SOLUTION FOR INJECTION 25MG	3685/22T	021775	IBSA FARMACEUTICI ITALIA SRL	B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes
SOLIAN TABLET, FILM COATED 400MG	5318/22T	020095	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CARBOPLATIN/HOSPIRA SOLUTION FOR INFUSION 10MG/ML	2201/22T, 2202/22T, 2203/22T, 2204/22T, 2205/22T, 2206/22T, 2207/22T, 2208/22T, 5906/22T, 5907/22T, 5908/22T, 5909/22T, 5910/22T	012081	PFIZER HELLAS AE	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monogra A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for

				batch release, site where bat A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su
AMLORINE 10 TABLET 10MG	4963/22T	020259	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLORINE 5 TABLET 5MG	4964/22T	020258	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ISOPTO-MAXITROL EYE DROPS, SUSPENSION	4965/22T	017328	NOVARTIS IRELAND LIMITED	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
SORIL-MED ORANGE LOZENGE 2MG/0.60MG/1.20MG	5279/22T	022761	SAPIENS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CERNEVIT POWDER FOR SOLUTION FOR INJECTION	5843/22T, 5844/22T	018769	BAXTER (HELLAS) EPE	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES -

				FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
SORIL-MED LEMON LOZENGE 3MG	3509/22T, 3510/22T	022759	SAPIENS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ALZEDEM TABLET, FILM COATED 15MG	1565/22T	022256	CODAL-SYNTO LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation
ALZEDEM TABLET, FILM COATED 5MG	1563/22T	022254	CODAL-SYNTO LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation
ALZEDEM TABLET, FILM COATED 20MG	1566/22T	022257	CODAL-SYNTO LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation
ALZEDEM TABLET, FILM COATED 10MG	1564/22T	022255	CODAL-SYNTO LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation

SNIP TABLET	1785/22T	020113	MEDOCHE MIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	2440/22T, 2441/22T	019161	SANOFI-AVENTIS GROUPE	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	2436/22T, 2437/22T	019160	SANOFI-AVENTIS GROUPE	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or

				addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	2434/22T, 2435/22T	019159	SANOFI-AVENTIS GROUPE	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	2438/22T, 2439/22T	019744	SANOFI-AVENTIS GROUPE	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 A.1 - ADMINISTRATIVE CHANGES -

				Change in the name and/or address of the marketing authorisation holder
YANIMO RESPIMAT SOLUTION FOR INHALATION	6059/21T, 6060/21T, 6061/21T, 6062/21T, 6063/21T	022387	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit
SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	6064/21T, 6065/21T, 6066/21T, 6067/21T, 6068/21T	022379	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.2.c.1 B.II.b.2.c.1 -

				QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	9811/21T	019161	SANOFI-AVENTIS GROUPE	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	9812/21T	019160	SANOFI-AVENTIS GROUPE	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	9810/21T	019744	SANOFI-AVENTIS GROUPE	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	9809/21T	019159	SANOFI-AVENTIS GROUPE	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	5360/22T, 5361/22T, 5362/22T	019161	SANOFI-AVENTIS GROUPE	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	5366/22T, 5367/22T, 5368/22T	019160	SANOFI-AVENTIS GROUPE	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	5363/22T, 5364/22T, 5365/22T	019744	SANOFI-AVENTIS GROUPE	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	5369/22T, 5370/22T, 5371/22T	019159	SANOFI-AVENTIS GROUPE	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
VOLTAREN EMUGEL GEL 1%	8244/21T, 8245/21T, 8246/21T, 8247/21T, 8248/21T	018989	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for

				batch release, site where bat A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities
HYDROCHLOROTHIAZIDE TABLET 50MG	5829/22T	008553	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	4256/22T	022376	TEVA GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

				test procedure for the finished product - Other changes
PLATOREL TABLET, FILM COATED 5MG	5497/22T	022553	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PLATOREL TABLET, FILM COATED 20MG	5495/22T	022555	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PLATOREL TABLET, FILM COATED 40MG	5494/22T	022556	ELPEN PHARMACEU	B.III.1.a.2 B.III.1.a.2 - QUALITY

			TICAL CO INC	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PLATOREL TABLET, FILM COATED 10MG	5496/22T	022554	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GRACIAL TABLET	547/22T, 548/22T	018377	ASPEN PHARMA TRADING LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	4028/21T, 4029/21T, 4030/21T	022511	SANOFI PASTEUR.	B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.I.b.1.g B.I.b.1.g - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the

				finished product, including an intermediate used A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used
VOLTAREN SUPPOSITORY 100MG	1835/22T, 1836/22T, 1837/22T, 1838/22T, 1839/22T, 1840/22T, 1841/22T, 1842/22T	018400	NOVARTIS IRELAND LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificat B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufactur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance w A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o B.I.c.2.z B.I.c.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in the specification parameters and/or limits of the immediate packaging
VOLTAREN FOR CHILDREN SUPPOSITORY 12.5MG	1819/22T, 1820/22T, 1821/22T, 1822/22T, 1823/22T, 1824/22T, 1825/22T, 1826/22T	018454	NOVARTIS IRELAND LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificat B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/int ermediate used in the manufactur B.I.d.1.a.4

				B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance w A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o B.I.c.2.z B.I.c.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in the specification parameters and/or limits of the immediate packaging
VOLTAREN SUPPOSITORY 50MG	1827/22T, 1828/22T, 1829/22T, 1830/22T, 1831/22T, 1832/22T, 1833/22T, 1834/22T	018443	NOVARTIS IRELAND LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificat B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting

				material/reagent/intermediate used in the manufactur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance w A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o B.I.c.2.z B.I.c.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in the specification parameters and/or limits of the immediate packaging
LEVOXA TABLET, FILM COATED 500MG	3386/22T	021993	ACTAVIS GROUP PTC EHF	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LYSOSPRAY OROMUCOSAL SPRAY 2.5MG/ACTUATION	10484/20T	022023	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
MUCOSOLVAN SYRUP 30MG/5ML	10481/20T	021127	OPELLA HEALTHCARE GREECE SINGLE	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL

			MEMBER LTD (OPELLA E.P.E.)	ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
MUCOSOLVAN PROLONGED RELEASE CAPSULES 75MG	10479/20T	019781	OPELLA HEALTHCAR E GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
MUCOSOLVAN SYRUP 15MG/5ML	10483/20T	011682	OPELLA HEALTHCAR E GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
MUCOSOLVAN SOLUTION FOR INJECTION 7.5MG/ML, 2ML VIALS	10482/20T	011681	OPELLA HEALTHCAR E GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
MUCOSOLVAN ORAL GUM 15MG	10480/20T	020696	SANOFI AVENTIS AEBE	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
IMATINIB REMEDICA TABLET, FILM COATED 400MG	4707/22T	021688	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
IMATINIB REMEDICA TABLET, FILM COATED 100MG	4708/22T	021687	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MEDOPRAZOLE GASTRO-RESISTANT CAPSULE, HARD 20MG	5284/22T	017551	MEDOCHEMIE LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
ONCOTICE POWDER FOR SOLUTION FOR INFUSION	5256/22T, 5257/22T	019017	MSD AFVEE	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a

				manufacturer of a novel excipient (where specified in the technical dossier) A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
ZYLORIC TABLET 300MG	5296/22T	019525	ASPEN PHARMA TRADING LIMITED	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
NIZORAL SHAMPOO 20MG/G	4436/22T	012220	STADA ARZNEIMITTEL AG	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
NIZORAL SHAMPOO 20MG/G	3163/22T	012220	STADA ARZNEIMITTEL AG	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
IMATINIB REMEDICA TABLET, FILM COATED 400MG	4199/22T	021688	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
IMATINIB REMEDICA TABLET, FILM COATED 100MG	4198/22T	021687	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZYLAPOUR TABLET 300MG	8591/21T	016544	IASIS PHARMACEUTICALS HELLAS SA	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change in the specification parameters and/or limits of the finished product to more accurately describe the appearance of the drug product
IRINOTECAN VENUS CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	9264/21T	023095	VENUS PHARMA GMBH	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 -

				Implementation of wording agreed by the competent authority
MAALOX PLUS ORAL SUSPENSION	3573/21T	019265	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MAALOX PLUS ORAL SUSPENSION	3573/21T	019265	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BATRAFEN MEDICATED NAIL LACQUER 8% W/W	3575/21T	016139	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MAALOX ORAL SUSPENSION (22.8+40)MG/ML	3572/21T	019266	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MAALOX ORAL SUSPENSION (22.8+40)MG/ML	3572/21T	019266	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MAALOX PLUS TABLET, CHEWABLE	3574/21T	019267	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MAALOX PLUS TABLET, CHEWABLE	3574/21T	019267	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TELFAST TABLET, FILM COATED 180MG	3571/21T	018151	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MEDOPEXOL TABLET 0.18MG	4134/22T	020556	MEDOCHEMIE LTD	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release

MEDOPEXOL TABLET 0.7MG	4135/22T	020557	MEDOCHE MIE LTD	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
MEDOPEXOL TABLET 0.088MG	4133/22T	020555	MEDOCHE MIE LTD	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
TORVACARD NEO TABLET, FILM COATED 20MG	3079/22T, 3080/22T	022248	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TORVACARD NEO TABLET, FILM COATED 80MG	3075/22T, 3076/22T	022250	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TORVACARD NEO TABLET, FILM COATED 40MG	3077/22T, 3078/22T	022249	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TORVACARD NEO TABLET, FILM COATED 10MG	3081/22T, 3082/22T	022247	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	8636/20T	017527	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b.1 c) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products or for pharmaceutical forms manufactured by complex manufacturing processes
LAMISIL TABLET 250MG	8145/21T	018385	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
CILOXAN EYE DROPS, SOLUTION 0.3% W/V	7498/21T, 7499/21T, 7500/21T, 7501/21T	019630	NOVARTIS IRELAND LIMITED	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible

				include batch release B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PANTOGAR CAPSULE, HARD	163/22T	019187	MERZ PHARMACEUTICALS GMBH	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)
PANTOGAR CAPSULE, HARD	163/22T	019187	MERZ PHARMACEUTICALS GMBH	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)

CLOPIDOGREL ACCORD TABLET, FILM COATED 75MG	1942/22T	021757	ACCORD HEALTHCARE S.L.U	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
PROSPAN COUGH SYRUP 7MG/ML	4672/22T, 4673/22T	019434	ENGELHARD ARZNEIMITTEL GMBH & CO. KG	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
FLAGYMET GRANULES 400MG	8275/21T	023073	VERISFIELD SINGLE MEMBER S.A.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where

				relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
DONEPEZIL ACCORD TABLET, FILM COATED 10MG	1576/22T	021472	ACCORD HEALTHCARE S.L.U	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
DONEPEZIL ACCORD TABLET, FILM COATED 5MG	1575/22T	021471	ACCORD HEALTHCARE S.L.U	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
TOBRADEX EYE OINTMENT	3246/22T	017323	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TIOTROPIUM DEMO INHALATION POWDER, HARD CAPSULE 18MCG	3889/22T	023456	DEMO S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES -

				Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
IMAREM TABLET, FILM COATED 100MG	4197/22T	021689	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
IMAREM TABLET, FILM COATED 400MG	4196/22T	021690	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the

				outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AGREGEX TABLET, FILM COATED 75MG	11037/20T, 11038/20T	20666	TEVA BV	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
OCTAGAM SOLUTION FOR INFUSION 10%	2389/22T	020717	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance

MEDOFLUCON CAPSULE, HARD 150MG	1536/22T	012701	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MEDOFLUCON CAPSULE, HARD 50MG	1535/22T	012700	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MEDOFLUCON CAPSULE, HARD 200MG	1537/22T	019830	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
OCTAGAM SOLUTION FOR INFUSION 10%	1373/22T	020717	OCTAPHARMA (IP) SPRL	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
EUVASCOR CAPSULE, HARD 10MG/5MG	9375/21T	022858	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the

				relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EUVASCOR CAPSULE, HARD 20MG/5MG	9376/21T	022859	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EUVASCOR CAPSULE, HARD 40MG/5MG	9377/21T	022860	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

EUVASCOR CAPSULE, HARD 40MG/10MG	9380/21T	022863	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EUVASCOR CAPSULE, HARD 10MG/10MG	9378/21T	022861	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EUVASCOR CAPSULE, HARD 20MG/10MG	9379/21T	022862	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CARAMLO TABLET 5MG/8MG	4289/22T, 4290/22T, 4291/22T, 4292/22T, 4293/22T	022063	ZENTIVA K.S.	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the

				specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes
CARAMLO TABLET 10MG/16MG	4294/22T, 4295/22T, 4296/22T, 4297/22T, 4298/22T	022064	ZENTIVA K.S.	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance -

				Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes
SMOFKABIVEN LOW OSMO PERIPHERAL EMULSION FOR INFUSION	2796/22T	023281	FRESENIUS KABI HELLAS A.E.	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION	2797/22T	20667	FRESENIUS KABI HELLAS A.E.	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by

				the competent authority
SMOFKABIVEN ELECTROLYTE FREE EMULSION FOR INFUSION	2798/22T	020716	FRESENIUS KABI HELLAS AE	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
SMOFKABIVEN EMULSION FOR INFUSION	2799/22T	20651	FRESENIUS KABI HELLAS AE	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
OPTIVATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	4311/22T	021627	BPL BIOPRODUCTS LABORATORY GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File

				when changes do not affect the properties of the finished product
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 600IU	3037/22T	022503	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PENTASA PROLONGED RELEASE GRANULES 4G	3040/22T	022373	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1200IU	3038/22T	022504	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1200IU	3038/22T	022504	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1200IU	3038/22T	022504	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PENTASA PROLONGED RELEASE GRANULES 2G	3041/22T	021943	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PICOPREP POWDER FOR ORAL SOLUTION	3039/22T	021028	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PICOPREP POWDER FOR ORAL SOLUTION	3039/22T	021028	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	4242/22T	019691	NOVARTIS IRELAND LIMITED	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	4243/22T	019692	NOVARTIS IRELAND LIMITED	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
ZOVIDUO CREAM (50MG/10MG)/G	2529/22T, 2530/22T	022886	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (4G/0.5G)/VIAL	2864/22T, 2865/22T, 2866/22T	020530	MYLAN IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer

				responsible for importation and/or batch release - Not including batch control/testing A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (2G/0.25G)/VIAL	2861/22T, 2862/22T, 2863/22T	020529	MYLAN IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
PONSTAN FORTE TABLET, FILM COATED 500MG	2385/22T	019500	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SALUREX TABLET 40MG	9502/21T, 9503/21T	007733	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
METHOTREXATE/PFIZER TABLET 2.5MG	7353/21T	002904	PFIZER HELLAS AE	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
PULMOCLASE <<SUGAR FREE>> SYRUP 750MG/5ML	2587/22T	023544	OLVOS SCIENCE SA	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
LATAZ-CO EYE DROPS, SOLUTION (50MCG+5MG)/ML	5259/22T	022802	RAFARM S.A.	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
NORMOSANG CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	8006/20T	null	ORPHAN EUROPE SARL, FRANCE	C.I.11 b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
NORMOSANG CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	8727/21T	null	ORPHAN EUROPE SARL, FRANCE	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
CONVERIDE TABLET, FILM COATED 300MG/25MG	8110/21T	022219	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIDE TABLET, FILM COATED 300MG/12.5MG	8109/21T	022218	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIDE TABLET, FILM COATED 150MG/12.5MG	8108/21T	022217	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur.

				Monograph - Updated certificate from an already approved manufacturer
CONVERIDE TABLET, FILM COATED 300MG/25MG	7640/21T	022219	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIDE TABLET, FILM COATED 300MG/12.5MG	7639/21T	022218	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

CONVERIDE TABLET, FILM COATED 150MG/12.5MG	7638/21T	022217	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIDE TABLET, FILM COATED 300MG/12.5MG	9822/21T, 9823/21T	022218	MEDOCHE MIE LTD	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take

				place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
CONVERIDE TABLET, FILM COATED 150MG/12.5MG	9820/21T, 9821/21T	022217	MEDOCHE MIE LTD	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
CONVERIDE TABLET, FILM COATED 300MG/25MG	9824/21T, 9825/21T	022219	MEDOCHE MIE LTD	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a

				manufacturer responsible for importation and/or batch release - Including batch control/testing B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
VAXIGRIPTETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	844/22T	022512	SANOFI PASTEUR.	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
ORIZAL PLUS TABLET, FILM COATED 40/10/12.5MG	6914/21T, 6915/21T, 6916/21T, 6917/21T	021494	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	6902/21T, 6903/21T, 6904/21T, 6905/21T	021493	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	6898/21T, 6899/21T, 6900/21T, 6901/21T	021492	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

				Updated certificate from an already approved manufacturer B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	6910/21T, 6911/21T, 6912/21T, 6913/21T	021496	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.b.1.h B.I.b.1.h - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	6906/21T, 6907/21T, 6908/21T, 6909/21T	021495	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or

				limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue
NOSATEL SOLUTION FOR INJECTION OR INFUSION 50MG/2ML	2010/22T	020155	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
NOSATEL TABLET, FILM COATED 25MG	2011/22T, 2012/22T	020154	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
DEXAMETHASONE/KABI SOLUTION FOR INJECTION 4MG/ML	752/22T	023654	FRESENIUS KABI HELLAS AE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
DEXAMETHASONE/KABI SOLUTION FOR INJECTION 4MG/ML	2759/22T, 2760/22T	023654	FRESENIUS KABI HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)
AMLOBE TABLET 10MG	5247/22T	021193	TAD PHARMA GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a

				Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority.
AMLOBE TABLET 5MG	5248/22T	021192	TAD PHARMA GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority.
LATAZ EYE DROPS, SOLUTION 50MCG/1ML(0.005% W/V)	2889/22T	021150	RAFARM S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
LATAZ-CO EYE DROPS, SOLUTION (50MCG+5MG)/ML	2888/22T	022802	RAFARM S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SPIRO TABLET 25MG	1663/22T	020009	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SPIRO TABLET 100MG	1664/22T	020008	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CIPROFLOXACIN KABI SOLUTION FOR INFUSION 2MG/ML(200MG/100ML)	2875/22T	020160	FRESENIUS KABI HELLAS AE	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
LEVOFLOXACIN KABI SOLUTION FOR INFUSION 5MG/ML	2874/22T	20574	FRESENIUS KABI HELLAS AE	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
CIPROFLOXACIN KABI SOLUTION FOR INFUSION 2MG/ML(400MG/200ML)	2876/22T	020159	FRESENIUS KABI HELLAS AE	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
PROGRAF CAPSULE, HARD 0.5MG	5516/22T, 5517/22T, 5518/22T, 5519/22T, 5520/22T, 5521/22T, 5522/22T, 5523/22T, 5524/22T	022365	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.a.3.b.1

				B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients
PROGRAF CAPSULE, HARD 1MG	5498/22T, 5499/22T, 5500/22T, 5501/22T, 5502/22T, 5503/22T, 5504/22T, 5505/22T, 5506/22T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.a.3.b.1

				B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients
PROGRAF CAPSULE, HARD 5MG	5507/22T, 5508/22T, 5509/22T, 5510/22T, 5511/22T, 5512/22T, 5513/22T, 5514/22T, 5515/22T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.II.e.2.a B.II.e.2.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.a.3.b.1

				B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients
ZAOLIN CAPSULE, SOFT 80MG	2757/22T, 2758/22T	023154	PHARMAZAC S.A.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ZAOLIN CAPSULE, SOFT 30MG	2755/22T, 2756/22T	023153	PHARMAZAC S.A.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release B.II.d.2.a B.II.d.2.a

				- QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ZAOLIN CAPSULE, SOFT 20MG	2753/22T, 2754/22T	023152	PHARMAZAC S.A.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	5069/22T	null	ACCORD HEALTHCARE LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

				Updated certificate from an already approved manufacturer
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	5068/22T	null	ACCORD HEALTHCARE LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LUCIDEL PLUS TABLET, FILM COATED (300+12.5)MG	5313/22T	022180	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LUCIDEL PLUS TABLET, FILM COATED (300+25)MG	5315/22T	022181	ELPEN PHARMACEU	B.III.1.a.2 B.III.1.a.2 -

			TICAL CO INC	QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LUCIDEL PLUS TABLET, FILM COATED (150+12.5)MG	5314/22T	022179	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SORIL-MED ORANGE LOZENGE 2MG/0.60MG/1.20MG	3504/22T	022761	SAPIENS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer,

				batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
ATORVASTATIN KRKA TABLET, FILM COATED 30MG	1328/22T	021287	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATORVASTATIN KRKA TABLET, FILM COATED 10MG	1326/22T	20652	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

ATORVASTATIN KRKA TABLET, FILM COATED 20MG	1327/22T	20653	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATORVASTATIN KRKA TABLET, FILM COATED 80MG	1331/22T	021289	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATORVASTATIN KRKA TABLET, FILM COATED 40MG	1329/22T	20654	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATORVASTATIN KRKA TABLET, FILM COATED 60MG	1330/22T	021288	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	3452/22T	022396	SANOFI PASTEUR.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
CIPROXIN TABLET, FILM COATED 500MG	9668/20T	011264	BAYER HELLAS ABEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
CIPROXIN TABLET, FILM COATED 500MG	8125/21T	011264	BAYER HELLAS ABEE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
EUVASCOR CAPSULE, HARD 10MG/5MG	5830/21T	022858	LES LABORATOIRES SERVIER	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further

				substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
EUVASCOR CAPSULE, HARD 20MG/5MG	5825/21T	022859	LES LABORATOIRES SERVIER	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
EUVASCOR CAPSULE, HARD 40MG/10MG	5828/21T	022863	LES LABORATOIRES SERVIER	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
EUVASCOR CAPSULE, HARD 40MG/5MG	5826/21T	022860	LES LABORATOIRES SERVIER	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
EUVASCOR CAPSULE, HARD 10MG/10MG	5827/21T	022861	LES LABORATOIRES SERVIER	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
EUVASCOR CAPSULE, HARD 20MG/10MG	5829/21T	022862	LES LABORATOIRES SERVIER	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk

				management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
CLARITHROMYCIN AUROBINDO TABLET, FILM COATED 500MG	5107/22T	022191	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.4 B.III.1.a.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material)
DAPTOMYCIN NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 350MG/VIAL	3598/22T	023322	NORIDEM ENTERPRISES LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
DAPTOMYCIN NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	3599/22T	023323	NORIDEM ENTERPRISES LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MAINTELYTE SOLUTION FOR INFUSION 50G/L	2251/22T	023215	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ARIPIPRAZOLE AUROBINDO TABLET 15MG	7984/21T, 7985/21T	022293	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ARIPIPRAZOLE AUROBINDO TABLET 30MG	7986/21T, 7987/21T	022294	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ARIPIPRAZOLE AUROBINDO TABLET 10MG	7982/21T, 7983/21T	022292	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VISPRING ADVANCE EYE DROPS, SOLUTION 0.5MG/ML	2705/22T, 2706/22T	023286	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
BUSCOFEM CAPSULE, SOFT 400MG	5142/22T	022424	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PARACETAMOL ACCORD TABLET 500MG	null	022579	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the

				outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SIRANALEN ORAL SOLUTION 20MG/ML	6719/21T	022680	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PROGRAF CAPSULE, HARD 0.5MG	4364/22T, 4365/22T	022365	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to

				implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PROGRAF CAPSULE, HARD 1MG	4360/22T, 4361/22T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	4358/22T, 4359/22T	019080	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to

				implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PROGRAF CAPSULE, HARD 5MG	4362/22T, 4363/22T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
INFLUVAC SUB-UNIT TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	3388/22T	022692	MYLAN IRE HEALTHCARE LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BORTEZOMIB/TEVA POWDER FOR SOLUTION FOR INJECTION 3.5MG/VIAL	4466/22T	023019	TEVA BV	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible

				do not include batch release
VORICONAZOLE FRESENIUS KABI POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	2056/22T	022460	FRESENIUS KABI HELLAS A.E.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FIXAPROST EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (50MCG/5MG)/ML	2802/22T	023359	LABORATOIRES THEA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

BICALUTAMIDE ACCORD TABLET, FILM COATED 50MG	1342/22T	020794	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 5MG/ML	8040/20T	023491	B. BRAUN MELSUNGEN AG	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority, e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH.
MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 1MG/ML	8041/20T	023490	B. BRAUN MELSUNGEN AG	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority, e.g. a Core SmPC, following the assessment of an

				Urgent Safety Restriction etc. Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH.
MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 5MG/ML	2731/22T	023491	B. BRAUN MELSUNGEN AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 1MG/ML	2732/22T	023490	B. BRAUN MELSUNGEN AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

LAVIFENT PATCH, TRANSDERMAL 50MCG/HOUR	2404/22T, 2405/22T	020840	LAVIPHARM A.E.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

LAVIFENT PATCH, TRANSDERMAL 100MCG/HOUR	2400/22T, 2401/22T	020842	LAVIPHARM A.E.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

LAVIFENT PATCH, TRANSDERMAL 75MGG/HOUR	2402/22T, 2403/22T	020841	LAVIPHARM A.E.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

LAVIFENT PATCH, TRANSDERMAL 25MCG/HOUR	2406/22T, 2407/22T	020839	LAVIPHARM A.E.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

GABAPENTIN ACCORD CAPSULE, HARD 400MG	4400/22T	022567	ACCORD HEALTHCARE S.L.U	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
GABAPENTIN ACCORD CAPSULE, HARD 300MG	4401/22T	022566	ACCORD HEALTHCARE S.L.U	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of

				wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
BILAZ TABLET 20MG	2710/22T	021475	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
PRETERAX TABLET, FILM COATED 10MG/2.5MG	2752/22T	20661	LES LABORATOIRES SERVIER	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	757/22T	023239	SANOFI PASTEUR.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
EFLUELDA SUSPENSION FOR INJECTION IN PRE-	3296/22T	023239	SANOFI PASTEUR.	B.I.a.2.c B.I.a.2.c - QUALITY

FILLED SYRINGE 60MCG/DOSE				CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol
EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	9815/21T, 9816/21T	023239	SANOFI PASTEUR.	B.I.c.1.b B.I.c.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in immediate packaging of the active substance - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological active substances B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal

				product and is not related to a protocol
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	4184/22T	020571	MUNDIPHARMA PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	4182/22T	020573	MUNDIPHARMA PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	4183/22T	020572	MUNDIPHARMA PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	4185/22T	020570	MUNDIPHARMA PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active

				substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CONVERIDE TABLET, FILM COATED 300MG/25MG	847/22T	022219	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CONVERIDE TABLET, FILM COATED 300MG/12.5MG	846/22T	022218	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR

				or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CONVERIDE TABLET, FILM COATED 150MG/12.5MG	845/22T	022217	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
BETASERC TABLET, ORODISPERSIBLE 24MG	1745/22T	022394	MYLAN IRE HEALTHCARE LIMITED	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in

				the Pharmacovigilance System Master File (PSMF) location
TICOVAC SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.5ML/DOSE	3710/22T	023266	PFIZER HELLAS AE	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
TICOVAC JUNIOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.25ML/DOSE	3711/22T	023267	PFIZER HELLAS AE	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
ZOVIDUO CREAM (50MG/10MG)/G	2025/22T	022886	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur.

				Monograph - Updated certificate from an already approved manufacturer
FIXAPROST EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (50MCG/5MG)/ML	908/22T, 909/22T, 910/22T	023359	LABORATOIRES THEA	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing

				process of the active substance
FEMARA TABLET, FILM COATED 2.5MG	1685/21T, 1686/21T	018468	NOVARTIS IRELAND LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	3935/22T, 3936/22T	021927	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VENLAXIN TABLET, PROLONGED-RELEASE 225MG	5306/22T	021937	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
VENLAXIN TABLET, PROLONGED-RELEASE 150MG	5307/22T	021936	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
VENLAXIN TABLET, PROLONGED-RELEASE 75MG	5308/22T	021935	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size

PHOXILIUM SOLUTION FOR HAEMOFILTRATION, HAEMODIAFILTRATION AND HAEMODIALYSIS	4120/21T	20655	BAXTER HOLDING B.V.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AXETINE TABLET, FILM COATED 500MG	4779/22T	020763	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
AXETINE TABLET, FILM COATED 250MG	4780/22T	020762	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
CLARISCAN SOLUTION FOR INJECTION 0.5MMOL/ML	3270/22T, 3271/22T	022730	GE HEALTHCARE AS	B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that affects the product information B.II.e.4.c B.II.e.4.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products
PROGRAF CAPSULE, HARD 0.5MG	4139/22T	022365	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	4141/22T	019080	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer

				(including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
PROGRAF CAPSULE, HARD 1MG	4142/22T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
PROGRAF CAPSULE, HARD 5MG	4140/22T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active

				substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
BUDENOFALK UNO GASTRO-RESISTANT GRANULES 9MG	2666/22T	022433	DR. FALK PHARMA GMBH	B.II.a.3.a.1 B.II.a.3.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Addition , deletion or replacement
ABIDALO TABLET, FILM COATED 2.5MG	3554/22T	023561	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation

ABIDALO TABLET, FILM COATED 5MG	3555/22T	023562	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
TAZOCIN EF POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/VIAL	5849/21T	014384	PFIZER HELLAS AE	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
TAZOCIN EF POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/VIAL	3325/22T, 3326/22T	014384	PFIZER HELLAS AE	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or

				limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.2.z B.I.b.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other variation
EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	739/22T	023239	SANOFI PASTEUR.	B.II.c.1.b B.II.c.1.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method
PROGRAF CAPSULE, HARD 0.5MG	4138/22T	022365	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release

PROGRAF CAPSULE, HARD 1MG	4136/22T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
PROGRAF CAPSULE, HARD 5MG	4137/22T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	4628/22T	023231	BAUSCH + LOMB IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TAVANIC TABLET, FILM COATED 500MG	5526/22T	019283	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GRANULOKINE SINGLEJECT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 30 MU (0,6 MG/ML)	11080/20T, 6373/21T	019765	AMGEN EUROPE B.V.	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk

				management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GRANULOKINE SINGLEJECT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 48 MU (0,96 MG/ML)	11079/20T, 6372/21T	019766	AMGEN EUROPE B.V.	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GRANULOKINE SOLUTION FOR INJECTION 0.3MG/ML VIAL	11081/20T, 6374/21T	019764	AMGEN EUROPE B.V.	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	8732/21T	019692	NOVARTIS IRELAND LIMITED	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or

				storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	8731/21T	019691	NOVARTIS IRELAND LIMITED	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
GLICRON MODIFIED-RELEASE TABLET 60MG	5417/22T	022728	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GLICRON MODIFIED-RELEASE TABLET 30MG	5418/22T	022727	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
VILDAGLIPTIN PHARMATHEN TABLET 50MG	1258/22T	023063	PHARMATHEN S.A.	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
ZESTAVAL TABLET, FILM COATED 200MG	4806/22T	013365	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 600IU	4982/22T	022503	FERRING HELLAS MEPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1200IU	4981/22T	022504	FERRING HELLAS MEPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GENEMENT TABLET, FILM COATED 5MG	4969/22T	023123	GENEPHARM SA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
GENEMENT TABLET, FILM COATED 20MG	4968/22T	023124	GENEPHARM SA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including

				contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML	5255/22T	018413	NOVARTIS IRELAND LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
INFLUVAC SUB-UNIT TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	4279/22T	022692	MYLAN IRE HEALTHCAR E LIMITED	B.I.a.5.a B.I.a.5.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes to the active substance of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza
NIDAGYL CAPSULE, HARD 500MG	4883/22T	016855	DELORBIS PHARMACEU TICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosi milar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional

				data is required to be submitted by the MAH
EXTRANEAL SOLUTION FOR PERITONEAL DIALYSIS	1920/22T, 1921/22T, 1922/22T, 1923/22T	023288	BAXTER (HELLAS) EPE	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and im B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
ANAGRELIDE AOP CAPSULE, HARD 0.5MG	5348/22T	023145	AOP ORPHAN PHARMACEUTICALS GMBH	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a

				manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	3560/22T	023032	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 50MG/12.5MG	3559/22T	023031	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
NEBIDO SOLUTION FOR INJECTION 1000MG/4ML	9202/21T, 9203/21T	019681	BAYER HELLAS ABEE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PERSANTIN TABLET, COATED 75MG	3117/22T	003137	GLENWOOD GMBH	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TENOVIRAL TABLET, FILM COATED 204MG	4937/22T, 4938/22T, 4939/22T, 4940/22T, 4941/22T	022350	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where r B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the

				active substance - Minor change to the restricted part of an Active Substance Master File
TENOVIRAL TABLET, FILM COATED 123MG	4947/22T, 4948/22T, 4949/22T, 4950/22T, 4951/22T	022348	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where r B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an

				Active Substance Master File
TENOVIRAL TABLET, FILM COATED 163MG	4942/22T, 4943/22T, 4944/22T, 4945/22T, 4946/22T	022349	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where r B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File

TENOVIRAL TABLET, FILM COATED 245MG	4932/22T, 4933/22T, 4934/22T, 4935/22T, 4936/22T	022351	REMEDICA LTD	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where r B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of th B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
ACTILYSE CATHFLO POWDER FOR SOLUTION	6594/21T, 6595/21T, 6596/21T, 6597/21T,	023354	BOEHRINGER INGELHEIM	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES -

FOR INJECTION/INFUSION 2MG	6598/21T, 6599/21T, 6600/21T		HELLAS SINGLE MEMBER S.A.	ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
ACTILYSE POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1MG/ML	6601/21T, 6602/21T, 6603/21T, 6604/21T, 6605/21T, 6606/21T, 6607/21T	023353	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished

				product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
ACTILYSE POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1MG/ML	9066/21T, 9067/21T, 9068/21T, 9069/21T, 9070/21T, 9071/21T, 9072/21T, 9073/21T, 9074/21T	023353	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	B.II.b.1.c B.II.b.1.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b B.II.b.2.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place for a

				biological/immunological product and any of the test methods performed at the site is a biological/immunological method B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
FAMVIR TABLET, FILM COATED 125MG	3814/22T	016371	PHOENIX LABS UNLIMITED COMPANY	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
FAMVIR TABLET, FILM COATED 250MG	3815/22T	016080	PHOENIX LABS UNLIMITED COMPANY	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of

				Suitability is part of the approved dossier - Other variation
VILLAMOS TABLET, FILM COATED 5MG	3169/22T, 5338/22T, 5339/22T	021552	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				a generic/hybrid/biosimilar medicinal products following as
VILLAMOS TABLET, FILM COATED 5MG	3169/22T, 5338/22T, 5339/22T	021552	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS TABLET, FILM COATED 15MG	3172/22T, 5344/22T, 5345/22T	021554	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS TABLET, FILM COATED 15MG	3172/22T, 5344/22T, 5345/22T	021554	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product

				Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS TABLET, FILM COATED 10MG	3171/22T, 5342/22T, 5343/22T	021553	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS TABLET, FILM COATED 10MG	3171/22T, 5342/22T, 5343/22T	021553	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS TABLET, FILM COATED 20MG	3173/22T, 5346/22T, 5347/22T	021555	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS TABLET, FILM COATED 20MG	3173/22T, 5346/22T, 5347/22T	021555	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS TABLET, FILM COATED 2.5MG	3170/22T, 5340/22T, 5341/22T	021551	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS TABLET, FILM COATED 2.5MG	3170/22T, 5340/22T, 5341/22T	021551	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
DASATINIB/TEVA TABLET, FILM COATED 50MG	3429/22T, 3430/22T	023460	TEVA BV	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
DASATINIB/TEVA TABLET, FILM COATED 70MG	3431/22T, 3432/22T	023461	TEVA BV	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal

				products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
DASATINIB/TEVA TABLET, FILM COATED 20MG	3427/22T, 3428/22T	023459	TEVA BV	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
DASATINIB/TEVA TABLET, FILM COATED 100MG	3433/22T, 3434/22T	023462	TEVA BV	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
BERMOXEL TABLET 600MG	3914/22T	019838	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ASACOL ENEMA 4G/100ML	3470/22T	019627	TILLOTTS PHARMA GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished

				product - Change in test procedure for the finished product - Minor changes to an approved test procedure
CERNEVIT POWDER FOR SOLUTION FOR INJECTION	4663/22T	018769	BAXTER (HELLAS) EPE	C.I.10 C.I.10 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in the frequency and/or date of submission of periodic safety update reports (PSUR) for human medicinal products
VILLAMOS OD TABLET, ORODISPERSIBLE 10MG	3175/22T, 5330/22T, 5331/22T	021557	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS OD TABLET, ORODISPERSIBLE 15MG	3176/22T, 5332/22T, 5333/22T	021558	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS OD TABLET, ORODISPERSIBLE 5MG	3174/22T, 5328/22T, 5329/22T	021556	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
VILLAMOS OD TABLET, ORODISPERSIBLE 20MG	3177/22T, 5334/22T, 5335/22T	021559	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance dat C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following as
XALATAN EYE DROPS, SOLUTION 50MCG/ML	4931/22T	020805	UPJOHN HELLAS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CO-DIOVAN TABLET, FILM COATED 160/12.5MG	3746/22T	018977	NOVARTIS IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product,

				packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CO-DIOVAN TABLET, FILM COATED 160/25MG	3747/22T	019477	NOVARTIS IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CO-DIOVAN TABLET, FILM COATED 80/12.5MG	3745/22T	017851	NOVARTIS IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/12.5MG	4565/22T	023592	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/320MG/25MG	4563/22T	023594	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/25MG	4566/22T	023591	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/12.5MG	4567/22T	023590	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/25MG	4564/22T	023593	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
RUPAFIN TABLET 10MG	3328/22T	020316	J. URIACH Y COMPANIA S.A.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
RUPAFIN ORAL SOLUTION 1MG/ML	3327/22T	21571	J. URIACH Y COMPANIA S.A.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
CISATRACURIUM ACCORDPHARMA SOLUTION FOR INJECTION OR INFUSION 2MG/ML	2428/22T	023378	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the

				finished product - Replacement or addition of a site where batch control/testing takes place
OLARTAN TABLET, FILM COATED 40MG	2160/22T	019690	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
OLARTAN-PLUS TABLET, FILM COATED 20MG/12.5MG	2156/22T	020333	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
OLARTAN-PLUS TABLET, FILM COATED 40MG/12.5MG	2154/22T	021785	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ORIZAL PLUS TABLET, FILM COATED 40/10/12.5MG	2148/22T	021494	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	2147/22T	021493	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment

ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	2150/22T	021496	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	2146/22T	021492	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	2149/22T	021495	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to

				implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ORIZAL TABLET, FILM COATED 40MG/5MG	2152/22T	020613	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ORIZAL TABLET, FILM COATED 20MG/5MG	2151/22T	020612	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
OLARTAN TABLET, FILM COATED 10MG	2158/22T	019688	MENARINI INTERNATIONAL OPERATIONS	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

			LUXEMBOURG SA	VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
OLARTAN-PLUS TABLET, FILM COATED 40MG/25MG	2155/22T	021786	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ORIZAL TABLET, FILM COATED 40MG/10MG	2153/22T	020614	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by

				the competent authority that do not require any further assessment
OLARTAN TABLET, FILM COATED 20MG	2159/22T	019689	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
OLARTAN-PLUS TABLET, FILM COATED 20MG/25MG	2157/22T	020334	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
EZETIMIBE/MYLAN TABLET 10MG	3323/22T, 3324/22T	023155	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE

				CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	6690/21T	022534	BAYER HELLAS ABEE	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
GADOGRAF SOLUTION FOR INJECTION 1.0MMOL/ML	6689/21T	023258	BAYER HELLAS ABEE	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
GADOVIST PFS SOLUTION FOR INJECTION IN PREFILLED SYRINGES 1MMOL/ML	6691/21T	022535	BAYER HELLAS ABEE	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g.

				agreed wording + template change)
VALGANCICLOVIR ACCORD TABLET, FILM COATED 450MG	3303/22T	022452	ACCORD HEALTHCARE S.L.U	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
ATAZANAVIR ACCORD CAPSULE, HARD 300MG	762/21T	023147	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATAZANAVIR ACCORD CAPSULE, HARD 150MG	761/21T	023146	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product -

				Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FERINJECT SOLUTION FOR INJECTION OR INFUSION 50MG IRON/ML	8981/21T, 8982/21T	020795	VIFOR FRANCE	C.I.12 C.I.12 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Inclusion or deletion of black symbol and explanatory statements for medicinal products in the list of medicinal products that are subject to additional monitoring C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	8369/21T, 8370/21T, 8371/21T, 79/22T	018647	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification

				parameter (e.g. deletion of an obsolete parameter)
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	8366/21T, 8367/21T, 8368/21T, 78/22T	020252	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
FERINJECT SOLUTION FOR INJECTION OR INFUSION 50MG IRON/ML	9216/21T	020795	VIFOR FRANCE	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size
WILATE 500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	2531/22T, 2532/22T, 2533/22T	021812	OCTAPHARMA (IP) SPRL	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing

				authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
WILATE 1000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	2534/22T, 2535/22T, 2536/22T	021813	OCTAPHARMA (IP) SPRL	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
MONOPROST EYE DROPS, SOLUTION 50MCG/ML	2032/22T	022828	LABORATOIRES THEA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MONOPROST EYE DROPS, SOLUTION IN SINGLE DOSE CONTAINER 50MCG/ML	2033/22T	021947	LABORATOIRES THEA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VIRUCID TABLET 800MG	5237/22T	016290	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished

				product - Change in test procedure for the finished product - Minor changes to an approved test procedure
VIRUCID TABLET 400MG	5238/22T	016289	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
VIRUCID TABLET 200MG	5239/22T	016288	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
REVAMOX TABLET, FILM COATED 200MG	4858/22T	023581	GENEPHARM SA	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LACOSAMIDE/GENEPHARM TABLET, FILM COATED 200MG	714/22T	023118	GENEPHARM SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
LACOSAMIDE/GENEPHARM TABLET, FILM COATED 150MG	713/22T	023117	GENEPHARM SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
LACOSAMIDE/GENEPHARM TABLET, FILM COATED 100MG	712/22T	023116	GENEPHARM SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
LACOSAMIDE/GENEPHARM TABLET, FILM COATED 50MG	711/22T	023115	GENEPHARM SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF

SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML	4324/22T	018413	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML	4324/22T	018413	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SANDIMMUN NEORAL CAPSULE, SOFT 25MG	4327/22T	018439	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to

				implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SANDIMMUN NEORAL CAPSULE, SOFT 25MG	4327/22T	018439	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SANDIMMUN NEORAL CAPSULE, SOFT 100MG	4325/22T	018383	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SANDIMMUN NEORAL CAPSULE, SOFT 100MG	4325/22T	018383	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SANDIMMUN NEORAL CAPSULE, SOFT 50MG	4326/22T	018412	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SANDIMMUN NEORAL CAPSULE, SOFT 50MG	4326/22T	018412	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by

				the competent authority that do not require any further assessment
RISPERIDONE AUROBINDO TABLET, FILM COATED 3MG	6694/21T	023027	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RISPERIDONE AUROBINDO TABLET, FILM COATED 4MG	6695/21T	023028	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RISPERIDONE AUROBINDO TABLET, FILM COATED 2MG	6693/21T	023026	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RISPERIDONE AUROBINDO TABLET, FILM COATED 1MG	6692/21T	023025	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	9805/21T, 9806/21T	022396	SANOFI PASTEUR.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	3398/22T	null	ACCORD HEALTHCARE LIMITED	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	3399/22T	null	ACCORD HEALTHCARE LIMITED	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
BENYLIN MUCUS COUGH WARM HONEY & LEMON FLAVOUR SYRUP 20MG/ML	3238/21T	021632	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP

IONOLYTE SOLUTION FOR INFUSION	3938/22T, 3939/22T	022529	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ARIMIDEX TABLET, FILM COATED 1MG	3023/22T, 3024/22T, 3025/22T, 3026/22T, 3027/22T, 3028/22T	017100	LABORATOIRES JUVISE PHARMACEUTICALS	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specifi B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)
IONOLYTE SOLUTION FOR INFUSION	3501/22T	022529	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COVERSYL PLUS ARGININE TABLET, FILM COATED 2.5MG/0.625MG	9554/21T	020256	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PRETERAX TABLET, FILM COATED 5MG/1.25MG	9555/21T	020257	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PRETERAX TABLET, FILM COATED 10MG/2.5MG	9553/21T	20661	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 250MCG/10MCG	9758/21T	021397	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 50MCG/5MCG	9757/21T	021395	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 125MCG/5MCG	9759/21T	021396	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MAINTELYTE SOLUTION FOR INFUSION 50G/L	2456/22T	023215	BAXTER (HELLAS) EPE	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*

DICLODUO COMBI MODIFIED-RELEASE CAPSULE, HARD	4373/22T	022360	PHARMAS WISS CESKA REPUBLIKA SRO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML	4299/22T	018413	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
SANDIMMUN NEORAL CAPSULE, SOFT 25MG	4302/22T	018439	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer

				responsible for importation and/or batch release - Not including batch control/testing
SANDIMMUN NEORAL CAPSULE, SOFT 100MG	4300/22T	018383	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
SANDIMMUN NEORAL CAPSULE, SOFT 50MG	4301/22T	018412	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
ZITAMIN SOLUTION FOR INJECTION 5MG/ML	3056/22T	023021	NORIDEM ENTERPRISES LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process

ZITAMIN SOLUTION FOR INJECTION 2MG/ML	3059/22T	023020	NORIDEM ENTERPRISES LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
ZITAMIN SOLUTION FOR INJECTION 10MG/ML	3058/22T	023023	NORIDEM ENTERPRISES LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
ZITAMIN SOLUTION FOR INFUSION 2MG/ML	3060/22T	023024	NORIDEM ENTERPRISES LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
ZITAMIN SOLUTION FOR INJECTION 7.5MG/ML	3057/22T	023022	NORIDEM ENTERPRISES LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product,

				including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LATAZ-CO EYE DROPS, SOLUTION (50MCG+5MG)/ML	4720/22T	022802	RAFARM S.A.	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
LATAZ EYE DROPS, SOLUTION 50MCG/1ML(0.005% W/V)	4742/22T	021150	RAFARM S.A.	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient -

				European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
LASIX SOLUTION FOR INJECTION 20MG/2ML	5244/22T	019672	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LASIX TABLET 40MG	5245/22T	019673	SANOFI-AVENTIS GROUPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	3085/22T, 3086/22T	022376	TEVA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	3083/22T, 3084/22T	020187	TEVA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material,

				reagent or excipient (when mentioned in the dossier)* B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
LAMOTRIGINE ACCORD TABLET, CHEWABLE / DISPERSIBLE 25MG	491/22T	023557	ACCORD HEALTHCARE S.L.U	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LAMOTRIGINE ACCORD TABLET, CHEWABLE / DISPERSIBLE 100MG	492/22T	023558	ACCORD HEALTHCARE S.L.U	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LAMOTRIGINE ACCORD TABLET, CHEWABLE / DISPERSIBLE 5MG	490/22T	023556	ACCORD HEALTHCARE S.L.U	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TIOTROPIUM/MYLAN INHALATION POWDER, HARD CAPSULE 18MCG	3613/22T	023254	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
TIOTROPIUM/MYLAN INHALATION POWDER, HARD CAPSULE 18MCG	3250/22T	023254	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
DUODOPA INTESTINAL GEL	9363/21T	019725	ABBVIE PHARMACEUTICALS S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INTRATECT SOLUTION FOR INFUSION 100G/L	9310/21T	022263	BIOTEST PHARMA GMBH	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
INTRATECT SOLUTION FOR INFUSION 100G/L	9310/21T	022263	BIOTEST PHARMA GMBH	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a

				novel excipient (where specified in the technical dossier)
INTRATECT SOLUTION FOR INFUSION 50G/L	9311/21T	021466	BIOTEST PHARMA GMBH	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	4512/22T	022534	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CIPROXIN TABLET, FILM COATED 500MG	4517/22T	011264	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOGRAF SOLUTION FOR INJECTION 1.0MMOL/ML	4514/22T	023258	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (SINGLE DOSE)	4516/22T	022887	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (MULTIPLE DOSES)	4515/22T	022888	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
YASMIN TABLET, FILM COATED 0.03MG/3MG	4508/22T	022847	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
QLAIRA TABLET, FILM COATED	4509/22T	020525	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
YASMINELLE TABLET, FILM COATED 0.02MG/3MG	4507/22T	020125	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRIMOVIST SOLUTION FOR INJECTION IN PREFILLED SYRINGES 0.25MMOL/ML	4510/22T	019713	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AVELOX TABLET, FILM COATED 400MG	4519/22T	019636	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEBIDO SOLUTION FOR INJECTION 1000MG/4ML	4511/22T	019681	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOVIST PFS SOLUTION FOR INJECTION IN PREFILLED SYRINGES 1MMOL/ML	4513/22T	022535	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AVELOX SOLUTION FOR INFUSION 400MG/250ML	4518/22T	20658	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the

				name and/or address of the marketing authorisation holder
URSOFALK CAPSULE, HARD 250MG	3284/22T	009649	DR. FALK PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
URSOFALK ORAL SUSPENSION 250MG/5ML	3285/22T	020790	DR. FALK PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIUM TABLET 75MG	3869/22T, 3870/22T	020764	MEDOCHEMIE LTD	A.7 A.7 - ADMINISTRATIVE

				CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIUM TABLET 300MG	3873/22T, 3874/22T	020766	MEDOCHEMIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIUM TABLET 150MG	3871/22T, 3872/22T	020765	MEDOCHEMIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LONARID N TABLET (400+10+50) MG	4680/22T	019678	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
SMOFKABIVEN EXTRA NITROGEN ELECTROLYTE FREE EMULSION FOR INFUSION	508/22T	023283	FRESENIUS KABI HELLAS AE	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
SMOFKABIVEN EXTRA NITROGEN EMULSION FOR INFUSION	509/22T	023282	FRESENIUS KABI HELLAS AE	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
SMOFKABIVEN LOW OSMO PERIPHERAL EMULSION FOR INFUSION	506/22T	023281	FRESENIUS KABI HELLAS AE	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change

				in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
SMOFKABIVEN ELECTROLYTE FREE EMULSION FOR INFUSION	510/22T	020716	FRESENIUS KABI HELLAS AE	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION	507/22T	20667	FRESENIUS KABI HELLAS AE	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
SMOFKABIVEN EMULSION FOR INFUSION	511/22T	20651	FRESENIUS KABI HELLAS AE	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance

				where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
SALOFALK SUPPOSITORY 1G	2062/21T	020945	DR. FALK PHARMA GMBH	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
DELSITA TABLET, FILM COATED 50MG	4853/22T	023404	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
DELSITA TABLET, FILM COATED 25MG	4854/22T	023403	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
DELSITA TABLET, FILM COATED 100MG	4855/22T	023405	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
STAMARIL POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION IN PREFILLED SYRINGE	5697/21T	023176	SANOFI PASTEUR.	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including

				replacement or addition) for the active substance or a starting material/intermediate
ERTAPENEM APTAPHARMA POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 1G	9360/21T	023571	APTA MEDICA INTERNACIONAL D.O.O.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
UNIDROPS EYE DROPS, SOLUTION 20MG/ML	71/22T	022708	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MERSINOL TABLET, FILM COATED 10MG	9314/21T	021733	MEDOCHEMIE LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
MERSINOL TABLET, FILM COATED 20MG	9316/21T	021735	MEDOCHEMIE LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
MERSINOL TABLET, FILM COATED 5MG	9317/21T	021732	MEDOCHEMIE LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
MERSINOL TABLET, FILM COATED 15MG	9315/21T	021734	MEDOCHEMIE LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
IMODIUM PLUS TABLET 2MG/125MG	9057/21T	022813	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PHYSIONEAL 35 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86% W/V	9145/21T, 9146/21T, 9147/21T	022311	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

PHYSIONEAL 35 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	9151/21T, 9152/21T, 9153/21T	022309	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PHYSIONEAL 40 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	9139/21T, 9140/21T, 9141/21T	022313	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PHYSIONEAL 35 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	9148/21T, 9149/21T, 9150/21T	022310	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PHYSIONEAL 40 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86%	9136/21T, 9137/21T, 9138/21T	022314	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PHYSIONEAL 40 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	9142/21T, 9143/21T, 9144/21T	022312	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PLATOREL TABLET, FILM COATED 5MG	4334/22T, 4335/22T	022553	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
PLATOREL TABLET, FILM COATED 20MG	4330/22T, 4331/22T	022555	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active

				substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
PLATOREL TABLET, FILM COATED 40MG	4328/22T, 4329/22T	022556	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
PLATOREL TABLET, FILM COATED 10MG	4332/22T, 4333/22T	022554	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
ROSUVASTATIN ACINO TABLET, FILM COATED 20MG	4651/22T	022940	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the

				same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROSUVASTATIN ACINO TABLET, FILM COATED 5MG	4653/22T	022938	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROSUVASTATIN ACINO TABLET, FILM COATED 10MG	4652/22T	022939	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

ROSUVASTATIN ACINO TABLET, FILM COATED 40MG	4650/22T	022941	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VINBLASTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	5254/22T	012083	PFIZER HELLAS AE	B.II.e.3.a B.II.e.3.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure
ROSUVASTATIN ACINO TABLET, FILM COATED 20MG	9281/21T	022940	ACINO AG	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ROSUVASTATIN ACINO TABLET, FILM COATED 5MG	9279/21T	022938	ACINO AG	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ROSUVASTATIN ACINO TABLET, FILM COATED 10MG	9280/21T	022939	ACINO AG	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under

				Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ROSUVASTATIN ACINO TABLET, FILM COATED 40MG	9282/21T	022941	ACINO AG	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
DAREQ TABLET, FILM COATED 5MG	4714/22T	021529	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority
BORTEZOMIB STADA SOLUTION FOR INJECTION 2.5MG/ML	1262/22T	023431	STADA ARZNEIMITTEL AG	B.II.b.4.d B.II.b.4.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes
QUETIAPINE/GENERICS TABLET, FILM COATED 100MG	6419/21T	021522	MYLAN IRELAND LIMITED	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
QUETIAPINE/GENERICS TABLET, FILM COATED 25MG	6418/21T	021521	MYLAN IRELAND LIMITED	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
QUETIAPINE/GENERICS TABLET, FILM COATED 200MG	6420/21T	021523	MYLAN IRELAND LIMITED	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing

				process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
ZYRTEC ORAL SOLUTION 0.1%	2171/21T	016365	UCB PHARMA SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ZYRTEC TABLET, FILM COATED 10MG	2172/21T	013066	UCB PHARMA SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
NITROFURANTOIN/IASIS ORAL SUSPENSION 25MG/5ML	4994/22T	023237	IASIS PHARMACEUTICALS HELLAS SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ENTEVIREM TABLET, FILM COATED 0.5MG	4810/22T	022613	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ENTEVIREM TABLET, FILM COATED 1MG	4809/22T	022614	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
CARDAMLO TABLET 10MG	5316/22T	021300	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure

				concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CARDAMLO TABLET 5MG	5317/22T	021299	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REVAMOX TABLET, FILM COATED 200MG	4337/22T	023581	GENEPHARM SA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details)

				and/or changes in the Pharmacovigilance System Master File (PSMF) location
NEVIRAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	3973/22T	022623	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
BOSENTAN AUROBINDO TABLET, FILM COATED 62.5MG	6625/21T	022419	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BOSENTAN AUROBINDO TABLET, FILM COATED 125MG	6626/21T	022420	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal

				products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LEPONEX TABLET 25MG	4662/22T	018390	MYLAN IRE HEALTHCAR E LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LEPONEX TABLET 100MG	4661/22T	018389	MYLAN IRE HEALTHCAR E LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CANESTEN CREAM 1%	1205/22T	004757	BAYER HELLAS ABEE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+100)MCG/DOSE	4805/22T	021399	ELPEN PHARMACEU TICAL CO INC	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES -

				FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+500)MCG/DOSE	4803/22T	020862	ELPEN PHARMACEUTICAL CO INC	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+250)MCG/DOSE	4804/22T	020861	ELPEN PHARMACEUTICAL CO INC	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
VIDELMET TABLET, FILM COATED 50MG/1000MG	4435/22T	023639	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VIDELMET TABLET, FILM COATED 50MG/850MG	4434/22T	023638	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LOVAREM TABLET 20MG	4678/22T, 4679/22T	018243	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for

				batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DELSITA TABLET, FILM COATED 50MG	4767/22T	023404	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DELSITA TABLET, FILM COATED 25MG	4768/22T	023403	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DELSITA TABLET, FILM COATED 100MG	4766/22T	023405	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

VILDAGLIPTIN ACCORD TABLET 50MG	2417/22T	023190	ACCORD HEALTHCARE S.L.U	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
ZANEDIP TABLET, FILM COATED 20MG	2803/22T, 2804/22T, 2805/22T, 2806/22T, 2807/22T, 2808/22T, 2809/22T, 2810/22T, 4186/22T	022271	RECORDATI HELLAS PHARMACEUTICALS SA	B.V.b.1.z B.V.b.1.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Referral - Update of the quality dossier int B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an app B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test

				proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product
ZANEDIP TABLET, FILM COATED 10MG	2811/22T, 2812/22T, 2813/22T, 2814/22T, 2815/22T, 2816/22T, 2817/22T, 2818/22T, 4187/22T	022270	RECORDATI HELLAS PHARMACEUTICALS SA	B.V.b.1.z B.V.b.1.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Referral - Update of the quality dossier int B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an app B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test proc

				B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product
LOSAR PLUS TABLET, FILM COATED 50MG/12.5MG	4901/22T	020782	REMEDICA LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
UTROGESTAN CAPSULE, SOFT 100MG	7345/20T, 7346/20T, 7347/20T, 7348/20T	013736	BESINS HEALTHCARE IRELAND LTD	B.III.1 a) 2. Updated certificate from an already approved manufacturer A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
BETALOC ZOK TABLET, PROLONGED-RELEASE 200MG	4722/22T, 4723/22T, 4724/22T, 4725/22T, 4726/22T	011478	RECORDATI IRELAND LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second

				B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan
BETALOC ZOK TABLET, PROLONGED-RELEASE 50MG	4732/22T, 4733/22T, 4734/22T, 4735/22T, 4736/22T	016247	RECORDATI IRELAND LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the

				manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan
BETALOC ZOK TABLET, PROLONGED-RELEASE 100MG	4727/22T, 4728/22T, 4729/22T, 4730/22T, 4731/22T	011477	RECORDATI IRELAND LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan
BETALOC ZOK TABLET, PROLONGED-RELEASE 25MG	4737/22T, 4738/22T, 4739/22T, 4740/22T, 4741/22T	019670	RECORDATI IRELAND LTD	B.II.b.1.a B.II.b.1.a - QUALITY

				CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier

				of the active substan
NEOSTIGMIN SOLUTION FOR INJECTION 2.5MG/1ML	4900/22T	012403	COOPER SA	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
GABENIL CAPSULE, HARD 400MG	4474/22T	020135	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
GABENIL CAPSULE, HARD 300MG	4472/22T	020134	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
GABENIL CAPSULE, HARD 100MG	4473/22T	020133	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
KIVALA TABLET, FILM COATED	5232/22T	022346	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CALRECIA SOLUTION FOR INFUSION 100MMOL/L	6811/21T	023053	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	3597/22T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.e.2 B.I.e.2 - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Introduction of a post approval change management protocol related to the active substance
ALVESCO INHALATION SOLUTION, PRESSURISED 80MCG	9793/21T	020455	COVIS PHARMA EUROPE B.V.	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and

				taste or identification test for a colouring or flavouring material)
ALVESCO INHALATION SOLUTION, PRESSURISED 160MCG	9794/21T	020456	COVIS PHARMA EUROPE B.V.	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
ELOMEN SOLUTION FOR INFUSION (10MG/3MG)/ML	3928/22T	023289	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ALGOFEN TABLET 500MG	3475/22T	006546	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VOLTAREN TABLET, GASTRO-RESISTANT 50MG	9573/20T, 9574/20T, 9575/20T, 9576/20T, 9577/20T, 9578/20T, 9579/20T, 9580/20T, 9581/20T, 9582/20T, 9583/20T	018455	NOVARTIS IRELAND LIMITED	B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion o B.II.c.1.a B.II.c.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Tightening B.II.c.1.b B.II.c.1.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Addition o B.II.c.1.z B.II.c.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change

				in the specification parameters and/or limits of an excipient - Other chan B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (in B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test pro
AGREGEX TABLET, FILM COATED 75MG	3294/22T	20666	TEVA BV	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ALBIGONE TABLET 10MG	4888/22T	019855	CODAL-SYNTO LIMITED	B.II.a.z B.II.a.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Other variation
ROWACHOL CAPSULE, GASTRO-RESISTANT	4878/22T, 4879/22T, 4880/22T	019799	ROWA PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES -

				Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss
ROWATINEX CAPSULE, GASTRO-RESISTANT	4875/22T, 4876/22T, 4877/22T	019798	ROWA PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a

				starting material, reagent or excipient (when mentioned in the dossier)* B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss
PULMICORT NEBULISER SUSPENSION 0.25MG/ML	4929/22T, 4930/22T	014265	ASTRAZENECA AB	B.II.d.1.i B.II.d.1.i - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Ph. Eur. 2.9.40 Uniformity of dosage units is introduced to replace the currently registered method, either Ph. Eur. 2.9.5 (Uniformity of mass). or Ph. Eur. 2.9.6 (Uniformity of content) B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

				the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
PULMICORT NEBULISER SUSPENSION 0.5MG/ML	4927/22T, 4928/22T	014266	ASTRAZENECA AB	B.II.d.1.i B.II.d.1.i - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Ph. Eur. 2.9.40 Uniformity of dosage units is introduced to replace the currently registered method, either Ph. Eur. 2.9.5 (Uniformity of mass). or Ph. Eur. 2.9.6 (Uniformity of content) B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
LANOXIN PG TABLET 0.0625MG	4432/22T, 4433/22T	019787	ASPEN PHARMA TRADING LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSUVASTATIN/MYLAN TABLET, FILM COATED 10MG	531/22T	022929	MYLAN IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
ROSUVASTATIN/MYLAN TABLET, FILM COATED 40MG	533/22T	022931	MYLAN IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the

				outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
ROSUVASTATIN/MYLAN TABLET, FILM COATED 5MG	530/22T	022928	MYLAN IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
ROSUVASTATIN/MYLAN TABLET, FILM COATED 20MG	532/22T	022930	MYLAN IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under

				Articles 45 or 46 of Regulation 1901/2006 - Other variation
HEXALEN OROMUCOSAL SPRAY 0.2%	4437/22T, 4438/22T, 4439/22T	006780	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TAVER TABLET 200MG	4684/22T, 4685/22T, 4686/22T, 4687/22T, 4688/22T, 4689/22T, 4690/22T	007169	MEDOCHEMIE LTD	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State -

				Active substance A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
VOLTAREN RETARD SUSTAINED RELEASE TABLETS 100MG	8181/20T, 8182/20T, 8183/20T, 8184/20T, 8185/20T	018444	NOVARTIS IRELAND LIMITED	B.I.a.2 a) Minor change in the manufacturing process of the active substance A.4 Change in the name and/or address of a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of

				the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
VOLTAREN TABLET, GASTRO-RESISTANT 50MG	8191/20T, 8192/20T, 8193/20T, 8194/20T, 8195/20T	018455	NOVARTIS IRELAND LIMITED	B.I.a.2 a) Minor change in the manufacturing process of the active substance A.4 Change in the name and/or address of a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
VOLTAREN SR SUSTAINED RELEASE TABLETS 75MG	8186/20T, 8187/20T, 8188/20T, 8189/20T, 8190/20T	018459	NOVARTIS IRELAND LIMITED	B.I.a.2 a) Minor change in the manufacturing process of the active substance A.4 Change in the name and/or address of a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a

				manufacturer of a novel excipient (where specified in the technical dossier)
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (SINGLE DOSE)	6688/21T	022887	BAYER HELLAS ABEE	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (MULTIPLE DOSES)	6687/21T	022888	BAYER HELLAS ABEE	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (SINGLE DOSE)	2939/22T	022887	BAYER HELLAS ABEE	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where

				no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (MULTIPLE DOSES)	2938/22T	022888	BAYER HELLAS ABEE	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place
DAPRIL TABLET 20MG	3336/22T	013085	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DAPRIL TABLET 10MG	3335/22T	013084	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Other variation
DAPRIL TABLET 5MG	3337/22T	013083	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
GLYCERYL TRINITRATE STERILE CONCENTRATE 5MG/ML	4471/22T	013817	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TRIPAN TABLET, FILM COATED 5MG	4189/22T	023089	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIPAN TABLET, FILM COATED 20MG	4188/22T	022616	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 20MG	9676/21T	021780	TAD PHARMA GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 40MG	9677/21T	021781	TAD PHARMA GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	2951/22T, 2952/22T, 2953/22T	019161	SANOFI-AVENTIS GROUPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.e.5.c B.I.e.5.c -

				QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	2945/22T, 2946/22T, 2947/22T	019160	SANOFI-AVENTIS GROUPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change

				management protocol - Implementation of a change for a biological/immunological medicinal product B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	2942/22T, 2943/22T, 2944/22T	019159	SANOFI-AVENTIS GROUPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture -

				Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	2948/22T, 2949/22T, 2950/22T	019744	SANOFI-AVENTIS GROUPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
ALENDRONIC ACID ACCORD TABLET 70MG	3766/22T, 3767/22T, 3768/22T	020928	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites

				for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 1000IU	1755/22T, 1756/22T, 1757/22T, 1758/22T	022914	OCTAPHARMA (IP) SPRL	B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification

				parameter (e.g. deletion of an obsolete parameter) B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	1751/22T, 1752/22T, 1753/22T, 1754/22T	022913	OCTAPHARMA (IP) SPRL	B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g.

				deletion of an obsolete parameter) B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 1000IU	9808/21T	022914	OCTAPHARMA (IP) SPRL	B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	9807/21T	022913	OCTAPHARMA (IP) SPRL	B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/int

				ermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 1000IU	49/22T	022914	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	48/22T	022913	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALBUREX 5 SOLUTION FOR INFUSION 50G/L	1963/22T, 1964/22T	20629	CSL BEHRING GMBH	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	1965/22T, 1966/22T	20630	CSL BEHRING GMBH	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the

				finished product - Replacement or addition of a site where batch control/testing takes place
IONOLYTE SOLUTION FOR INFUSION	2239/22T	022529	FRESENIUS KABI HELLAS AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PLAZERON CAPSULE, HARD 20MG	4038/22T	018665	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
FLUOXETINE AUROBINDO CAPSULE, HARD 20MG	3898/22T	023333	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GLYCERINE SUPPOSITORIES FOR CHILDREN/ZARPIS SUPPOSITORY 1.2G/SUPP.	4812/22T	014981	COSTAKIS TSISIOS & CO. LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GLYCERINE MICROCLYSMAS FOR CHILDREN / ZARBIS MICROENEMA 2.1G/DOSE (2,5ML)	4813/22T	014982	COSTAKIS TSISIOS & CO. LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of the marketing authorisation holder
GLYCERINE MICROCLYSMA FOR ADULTS ENEMA 2.4G/DOSE (2,5ML)	4815/22T	014547	COSTAKIS TSISIOS & CO. LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GLYCERINE MICROCLYSMA FOR BABIES ENEMA 1.8G/DOSE (2,5ML)	4814/22T	014546	COSTAKIS TSISIOS & CO. LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GLYCERINE SUPPOSITORIES FOR BABIES/ZARBIS SUPPOSITORY 0.6G/SUPP.	4811/22T	014207	COSTAKIS TSISIOS & CO. LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GLYCERINE SUPPOSITORIES FOR ADULTS/ZARBIS SUPPOSITORY 2.4G/SUPP.	4816/22T	014208	COSTAKIS TSISIOS & CO. LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FIXAPROST EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (50MCG/5MG)/ML	63/22T	023359	LABORATOIRES THEA	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
LENALIDOMIDE STADA CAPSULE, HARD 25MG	3356/22T	023624	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)

LENALIDOMIDE STADA CAPSULE, HARD 15MG	3354/22T	023622	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
LENALIDOMIDE STADA CAPSULE, HARD 20MG	3355/22T	023623	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
LENALIDOMIDE STADA CAPSULE, HARD 7.5MG	3352/22T	023620	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
LENALIDOMIDE STADA CAPSULE, HARD 10MG	3353/22T	023621	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
LENALIDOMIDE STADA CAPSULE, HARD 2.5MG	3350/22T	023618	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

				test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
LENALIDOMIDE STADA CAPSULE, HARD 5MG	3351/22T	023619	STADA ARZNEIMITTEL AG	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
CANDESARTAN KRKA TABLET 8MG	2105/22T, 2106/22T, 2107/22T	021502	KRKA D.D. NOVO MESTO	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.a.3.a.2 B.II.a.3.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Increase or reduction B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product,

				including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
CARBOPLATIN/HOSPIRA SOLUTION FOR INFUSION 10MG/ML	4645/22T	012081	PFIZER HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	1135/22T	022522	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
DALTEX TABLET, FILM COATED 50MG/1000MG	2569/21T	022711	MEDOCHEMIE LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
DALTEX TABLET, FILM COATED 50MG/850MG	2568/21T	022710	MEDOCHEMIE LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
VILDAGLIPTIN ACCORD TABLET 50MG	2256/22T	023190	ACCORD HEALTHCARE S.L.U	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
MEDOPRED SOLUTION FOR INJECTION OR INFUSION 30MG/ML	4677/22T	021839	MEDOCHEMIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or

				supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TRIATEC TABLET 2.5MG	1369/22T	012904	SANOFI-AVENTIS GROUPE	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
TRIATEC TABLET 5MG	1370/22T	012905	SANOFI-AVENTIS GROUPE	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (SINGLE DOSE)	4516/22T	022887	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DOTAGRAF SOLUTION FOR INJECTION 0.5MMOL/ML (MULTIPLE DOSES)	4515/22T	022888	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FUNGUSTATIN CAPSULE, HARD 150MG	4193/20T	013273	PFIZER HELLAS AE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data.
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	4192/20T	013275	PFIZER HELLAS AE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
FUNGUSTATIN CAPSULE, HARD 150MG	1261/21T	013273	PFIZER HELLAS AE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	1262/21T	013275	PFIZER HELLAS AE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended

				to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
FUNGUSTATIN CAPSULE, HARD 150MG	3466/20T	013273	PFIZER HELLAS AE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	3467/20T	013275	PFIZER HELLAS AE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
FUNGUSTATIN CAPSULE, HARD 150MG	6377/21T, 6378/21T	013273	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	6379/21T, 6380/21T	013275	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet

				due to new quality, preclinical, clinical or pharmacovigilance data
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	5855/20T	013275	PFIZER HELLAS AE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
NIMM TABLET 100MG	4773/22T	017715	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MIRENA INTRA UTERINE SYSTEM 52MG (20MCG/24h)	3807/22T	018612	BAYER HELLAS ABEE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ESMERON SOLUTION FOR INJECTION 50MG/5ML	4465/22T	018110	MSD AFVEE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	1093/20T	019523	SANOFI PASTEUR.	B.II.d.2 c) Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol B.II.d.1 e) Change outside the approved specifications limits range
MAYMETSI TABLET, FILM COATED 50MG/1000MG	9833/21T, 9834/21T, 9835/21T	023375	TAD PHARMA GMBH	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer

				(including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C
MAYMETSI TABLET, FILM COATED 50MG/850MG	9836/21T, 9837/21T, 9838/21T	023374	TAD PHARMA GMBH	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C
CAPOLEV PLUS TABLET 32/12.5MG	4782/22T	021612	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CAPOLEV PLUS TABLET 32/25MG	4781/22T	021613	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CAPOLEV PLUS TABLET 16/12.5MG	4783/22T	021611	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site,

				manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CAPOLEV PLUS TABLET 8/12.5MG	4784/22T	021610	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	2568/22T	019691	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	2568/22T	019691	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer

				(including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	2569/22T	019692	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	2569/22T	019692	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active

				substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
COTRIM DS TABLET 800/160MG	4775/22T, 4776/22T	008531	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient

				(when mentioned in the dossier)*
COTRIM TABLET 400/80MG	4777/22T, 4778/22T	006484	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CLENIL FORTE INHALATION SOLUTION, PRESSURISED 250MCG/DOSE	4715/22T, 4716/22T	012678	CHIESI HELLAS A.E.B.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
BETAISODONA VAGINAL DOUCHE 10% W/V	1866/22T	019867	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA SCALP & SKIN CLEANSER SOLUTION 7.5% W/V	1871/22T	012330	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA SURGICAL SCRUB 7.5% W/V	1868/22T	019861	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA VAGINAL GEL 10% W/W	1870/22T	012884	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
BETAISODONA THROAT SPRAY OROMUCOSAL SPRAY 0.45% W/V	1869/22T	018736	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA ANTISEPTIC PAINT SOLUTION 10% W/V	1864/22T	019864	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA VAGINAL SUPPOSITORIES 200MG	1860/22T	019994	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA GARGLE/MOUTHWASH 1% W/V	1873/22T	012423	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA SKIN CLEANSER CUTANEOUS SOLUTION 4% W/V	1861/22T	013786	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA OINTMENT 10% W/W	1862/22T	019996	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA STANDARDISED SOLUTION 10% W/V	1867/22T	019992	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA CREAM 5% W/W	1872/22T	014789	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA ALCOHOLIC CUTANEOUS SOLUTION 10% W/V	1863/22T	019993	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETAISODONA DRY POWDER, CUTANEOUS SPRAY 2.5% W/W	1865/22T	019817	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ATACAND PLUS TABLET 16MG/12.5MG	9694/21T	019464	CHEPLAPHARM ARZNEIMITTEL GMBH.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority
ATACAND PLUS TABLET 32MG/12.5MG	9695/21T	021325	CHEPLAPHARM ARZNEIMITTEL GMBH.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ATACAND PLUS TABLET 32MG/25MG	9696/21T	021326	CHEPLAPHARM ARZNEIMITTEL GMBH.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of

				wording agreed by the competent authority
XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	2528/22T	022002	MERZ PHARMACEUTICALS GMBH	B.II.b.3.c B.II.b.3.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability
XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	2527/22T	022001	MERZ PHARMACEUTICALS GMBH	B.II.b.3.c B.II.b.3.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability
PULMOZYME NEBULISER SOLUTION 2500U/2.5ML	8315/21T, 8316/21T, 8317/21T, 8318/21T, 8319/21T, 8320/21T, 8321/21T, 8322/21T, 8323/21T, 8324/21T, 8325/21T, 8326/21T, 8327/21T, 8328/21T, 8329/21T, 8330/21T	023074	ROCHE (HELLAS) SA	B.I.c.1.c B.I.c.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in immediate packa B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.a.4.d B.I.a.4.d - QUALITY

				CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits a B.I.a.4.c B.I.a.4.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits a B.I.a.4.a B.I.a.4.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits a B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process o B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starti B.I.a.1.g B.I.a.1.g - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starti
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	1255/22T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b.3.c B.II.b.3.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability
CATAFLAM TABLET, COATED 50MG	7775/21T	018492	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
CATAFLAM TABLET, COATED 50MG	3891/22T	018492	NOVARTIS IRELAND LIMITED	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
MEDOFLUCON CAPSULE, HARD 50MG	4800/22T, 4801/22T	012700	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MEDOFLUCON CAPSULE, HARD 200MG	4798/22T, 4799/22T	019830	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved

				manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MEDOFLUCON CAPSULE, HARD 150MG	4796/22T, 4797/22T	012701	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a

				starting material, reagent or excipient (when mentioned in the dossier)*
BIVELEN TABLET, FILM COATED 7.5MG	4675/22T	023219	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BIVELEN TABLET, FILM COATED 5MG	4674/22T	023218	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TRISEQUENS TABLET, FILM COATED	4802/22T	013501	NOVO NORDISK HELLAS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT -

				Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
MIRATON CAPSULE, HARD 2MG	3934/22T	021061	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TRILEPTAL TABLET, FILM COATED 150MG	3933/22T	019109	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer

				(including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
TRILEPTAL TABLET, FILM COATED 300MG	3930/22T	018463	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of

				Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
TRILEPTAL TABLET, FILM COATED 600MG	3931/22T	018464	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
TRILEPTAL ORAL SUSPENSION 60MG/ML	3932/22T	019494	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer,

				batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
SYNTOPRIM TABLET 400/80MG	4769/22T, 4770/22T	019826	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DEANXIT TABLET, FILM COATED	4676/22T	021765	LUNDBECK HELLAS A.E.,CYPRUS	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
NAUTISOL TABLET 5MG	4743/22T	006550	MEDOCHE MIE LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
MEDAXONUM LIDO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500MG/VIAL	2380/22T, 2381/22T	022765	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MEDAXONUM LIDO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1G/VIAL	2382/22T, 2383/22T	022766	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MEDAXONUM LIDO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500MG/VIAL	2223/22T, 2224/22T, 2225/22T	022765	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MEDAXONUM LIDO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1G/VIAL	2226/22T, 2227/22T, 2228/22T	022766	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TREVUSIN CAPSULE, HARD 8MG	4683/22T	023388	DELORBIS PHARMACEUTICALS LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
TREVUSIN CAPSULE, HARD 4MG	4682/22T	023387	DELORBIS PHARMACEUTICALS LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY

				CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
TRANEXAMIC ACID TABLET, FILM COATED 500MG	4266/22T, 4267/22T	019921	REMEDICA LTD	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
MAALOX PLUS TABLET, CHEWABLE	4270/22T	019267	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	9391/21T, 9392/21T	022396	SANOFI PASTEUR.	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active

				substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol
MISOONE TABLET 400MCG	9530/21T	023175	EXELGYN	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
AMIKA-SYNTO SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	9313/20T	019842	CODAL-SYNTO LIMITED	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
AMIKA-SYNTO SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	9314/20T	019843	CODAL-SYNTO LIMITED	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
AMIKA-SYNTO SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	2188/22T	019842	CODAL-SYNTO LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AMIKA-SYNTO SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	2189/22T	019843	CODAL-SYNTO LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site,

				manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AMIKA-SYNTO SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	2210/22T	019842	CODAL-SYNTO LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
AMIKA-SYNTO SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	2209/22T	019843	CODAL-SYNTO LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in

				the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
AMIKA-SYNTO SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	9075/20T	019842	CODAL-SYNTO LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
AMIKA-SYNTO SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	9076/20T	019843	CODAL-SYNTO LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ADAGREL TABLET, FILM COATED 75MG	3446/22T	20668	SAPIENS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/40MG	2396/22T	023128	MYLAN IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/10MG	2394/22T	023126	MYLAN IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/20MG	2395/22T	023127	MYLAN IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
CLAVOMID TABLET, FILM COATED 625MG	4484/22T, 4485/22T, 4486/22T, 4487/22T, 4488/22T	019667	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national

				pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/12.5MG	3566/22T, 3567/22T, 3568/22T	023157	MYLAN IRELAND LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
OLMEDIPIN PLUS TABLET, FILM COATED 20MG/5MG/12.5MG	3563/22T, 3564/22T, 3565/22T	023156	MYLAN IRELAND LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New

				certificate from a new manufacturer (replacement or addition)
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/12.5MG	3569/22T, 3570/22T, 3571/22T	023158	MYLAN IRELAND LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/25MG	3575/22T, 3576/22T, 3577/22T	023160	MYLAN IRELAND LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/25MG	3572/22T, 3573/22T, 3574/22T	023159	MYLAN IRELAND LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
TELFAST TABLET, FILM COATED 180MG	4721/22T	018151	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SNIP TABLET	3471/22T	020113	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZINDOLIN TABLET, FILM COATED 500MG	4659/22T	020026	REMEDICA LTD	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits
ZINDOLIN TABLET, FILM COATED 250MG	4658/22T	013916	REMEDICA LTD	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or

				limits of the finished product - Tightening of specification limits
KORANDIL TABLET 20MG	1428/22T	012843	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
KORANDIL TABLET 10MG	1429/22T	012842	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
KORANDIL TABLET 5MG	1427/22T	012841	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
KORANDIL TABLET 20MG	1430/22T, 1431/22T, 1432/22T, 1433/22T, 1434/22T, 1435/22T, 1436/22T, 1437/22T, 1438/22T, 1439/22T, 1440/22T, 1441/22T, 1442/22T, 1443/22T, 1444/22T, 1445/22T, 1446/22T, 1447/22T, 1448/22T, 1449/22T, 1450/22T, 1451/22T, 1452/22T, 1453/22T, 1454/22T, 1455/22T, 1456/22T, 1457/22T, 1458/22T, 1459/22T, 1460/22T	012843	REMEDICA LTD	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRO B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED

				PRODUCT B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the a B.II.a.3.b.5 B.II.a.3.b.5 - QUALITY CHANGES - FINISHED PRO B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - C B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE -
KORANDIL TABLET 10MG	1461/22T, 1462/22T, 1463/22T, 1464/22T, 1465/22T, 1466/22T, 1467/22T, 1468/22T, 1469/22T, 1470/22T, 1471/22T, 1472/22T, 1473/22T, 1474/22T, 1475/22T, 1476/22T, 1477/22T, 1478/22T, 1479/22T, 1480/22T, 1481/22T, 1482/22T, 1483/22T, 1484/22T, 1485/22T, 1486/22T, 1487/22T, 1488/22T, 1489/22T	012842	REMEDICA LTD	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRO B.II.b.5.z B.II.b.5.z - QUALITY

				CHANGES - FINISHED PRODUCT B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the a B.II.a.3.b.5 B.II.a.3.b.5 - QUALITY CHANGES - FINISHED PRO B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - C B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE -

KORANDIL TABLET 5MG	1490/22T, 1491/22T, 1492/22T, 1493/22T, 1494/22T, 1495/22T, 1496/22T, 1497/22T, 1498/22T, 1499/22T, 1500/22T, 1501/22T, 1502/22T, 1503/22T, 1504/22T, 1505/22T, 1506/22T, 1507/22T, 1508/22T, 1509/22T, 1510/22T, 1511/22T, 1512/22T, 1513/22T, 1514/22T, 1515/22T, 1516/22T, 1517/22T	012841	REMEDICA LTD	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRO B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the a B.II.a.3.b.5 B.II.a.3.b.5 - QUALITY CHANGES - FINISHED PRO B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT B.II.d.1.d B.II.d.1.d - QUALITY CHANGES -

				FINISHED PRODUCT B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - C B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE -
NOOTROPIL SOLUTION FOR INJECTION 3G/15ML	3116/22T	013874	UCB PHARMA SA	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
KAPETRAL TABLET, FILM COATED 500MG	3493/22T, 3494/22T	021626	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
KAPETRAL TABLET, FILM COATED 150MG	3491/22T, 3492/22T	021625	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 -

				QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NORVASC CAPSULE, HARD 10MG	4652/20T	013775	UPJOHN HELLAS LTD	C.I.3 z) Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 Other variation
NORVASC CAPSULE, HARD 5MG	4653/20T	013774	UPJOHN HELLAS LTD	C.I.3 z) Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent

				authority under Articles 45 or 46 of Regulation 1901/2006 Other variation
MEROPAN CAPSULE, HARD 20MG	3520/22T, 3521/22T, 3522/22T, 3523/22T, 3524/22T	020013	CODAL SYNTO LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
RISPERIDONE-REMEDICA TABLET, FILM COATED 3MG	4477/22T	20640	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RISPERIDONE-REMEDICA TABLET, FILM COATED 4MG	4476/22T	20641	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RISPERIDONE-REMEDICA TABLET, FILM COATED 2MG	4478/22T	20639	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RISPERIDONE-REMEDICA TABLET, FILM COATED 1MG	4479/22T	20638	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RISPERIDONE-REMEDICA TABLET, FILM COATED 6MG	4475/22T	20642	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TENOVIRAL TABLET, FILM COATED 204MG	4481/22T	022350	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product -

				Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TENOVIRAL TABLET, FILM COATED 123MG	4483/22T	022348	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TENOVIRAL TABLET, FILM COATED 163MG	4482/22T	022349	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TENOVIRAL TABLET, FILM COATED 245MG	4480/22T	022351	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TEVETEN PLUS TABLET, FILM COATED 600MG/12.5MG	3165/22T	020235	VIATRIS HEALTHCARE GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BORTEZOMIB STADA SOLUTION FOR INJECTION 2.5MG/ML	6404/21T	023431	STADA ARZNEIMITTEL AG	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML	1716/22T, 1717/22T, 1718/22T, 1719/22T, 1720/22T, 1721/22T, 1722/22T	018413	NOVARTIS IRELAND LIMITED	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufactur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change

				in the re-test period/storage period or storage conditions of the active substance w B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificat A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with
SANDIMMUN NEORAL CAPSULE, SOFT 50MG	1702/22T, 1703/22T, 1704/22T, 1705/22T, 1706/22T, 1707/22T, 1708/22T	018412	NOVARTIS IRELAND LIMITED	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufactur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance w B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificat A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with
SANDIMMUN NEORAL CAPSULE, SOFT 25MG	1723/22T, 1724/22T, 1725/22T, 1726/22T, 1727/22T, 1728/22T, 1729/22T	018439	NOVARTIS IRELAND LIMITED	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufactur B.I.d.1.a.4

				B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance w B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificat A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with
SANDIMMUN NEORAL CAPSULE, SOFT 100MG	1709/22T, 1710/22T, 1711/22T, 1712/22T, 1713/22T, 1714/22T, 1715/22T	018383	NOVARTIS IRELAND LIMITED	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/int

				ermediate used in the manufactur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance w B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificat A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with
IRBESARTAN ACCORD TABLET, FILM COATED 150MG	2193/22T, 2194/22T	021645	ACCORD HEALTHCAR E S.L.U	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
RHESONATIV SOLUTION FOR INJECTION 625IU/ML	3614/22T	020158	OCTAPHARMA (IP) SPRL	B.II.h.z B.II.h.z - QUALITY CHANGES - FINISHED PRODUCT - Adventitious Agents Safety - Other variation
RHESONATIV SOLUTION FOR INJECTION 625IU/ML	5084/21T	020158	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.II.b.3.a B.II.b.3.a - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LEVOXA TABLET, FILM COATED 500MG	3578/22T	021993	ACTAVIS GROUP PTC EHF	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
NITRAZEPAM ACCORD TABLET 5MG	1943/22T	022397	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference

				product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CERTICAN TABLET 0.5MG	8189/21T	019643	NOVARTIS IRELAND LIMITED	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
CERTICAN TABLET 0.75MG	8190/21T	019644	NOVARTIS IRELAND LIMITED	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
CERTICAN TABLET 1MG	8191/21T	019645	NOVARTIS IRELAND LIMITED	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site

				where batch control/testing takes place
CERTICAN TABLET 0.25MG	8188/21T	019642	NOVARTIS IRELAND LIMITED	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
SEVOFLURANE-PIRAMAL INHALATION VAPOUR, LIQUID 100% V/V	3732/22T, 3733/22T	021303	PIRAMAL CRITICAL CARE B.V.	B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 360MG	2782/22T	022405	ACCORD HEALTHCARE S.L.U	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 180MG	2781/22T	022404	ACCORD HEALTHCARE S.L.U	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
ZOLOFT TABLET, FILM COATED 50MG	8349/21T	014677	UPJOHN HELLAS LTD	B.II.a.z B.II.a.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Other variation
ZOLOFT TABLET, FILM COATED 100MG	8350/21T	014678	UPJOHN HELLAS LTD	B.II.a.z B.II.a.z - QUALITY CHANGES - FINISHED PRODUCT -

				Description and composition - Other variation
OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	1903/22T	021927	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	1730/22T, 1731/22T, 1732/22T, 1733/22T	022396	SANOFI PASTEUR.	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele B.I.b.1.i B.I.b.1.i - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Where there is no monograph in the European Pharmacopoeia or the B.I.b.2.e B.I.b.2.e - QUALITY

				CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance o
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8882/21T, 8883/21T, 8884/21T	022396	SANOFI PASTEUR.	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
ESMERON SOLUTION FOR INJECTION 50MG/5ML	6148/21T	018110	MSD AFVEE	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in

				storage conditions of the finished product or the diluted/reconstituted product
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 2.3% GLUCOSE, 1.75MMOL/L CALCIUM	4120/22T, 4121/22T	023198	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 4.25% GLUCOSE, 1.75MMOL/L CALCIUM	4122/22T, 4123/22T	023197	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.5% GLUCOSE, 1.75MMOL/L CALCIUM	4124/22T, 4125/22T	023196	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BUSCOFEM CAPSULE, SOFT 400MG	3890/22T	022424	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIATEC PLUS TABLET 5MG/25MG	1256/22T	019071	SANOFI-AVENTIS GROUPE	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
NALTREXONE ACCORD TABLET, FILM COATED 50MG	9226/21T, 9227/21T	022584	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 4.25% GLUCOSE	4114/22T, 4115/22T	022580	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 2.3% GLUCOSE	4116/22T, 4117/22T	022582	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 1.5% GLUCOSE	4118/22T, 4119/22T	022581	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CO-DIOVAN TABLET, FILM COATED 160/12.5MG	1356/22T	018977	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
CO-DIOVAN TABLET, FILM COATED 160/25MG	1357/22T	019477	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
CO-DIOVAN TABLET, FILM COATED 80/12.5MG	1355/22T	017851	NOVARTIS IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS -

				Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	9416/21T	023447	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
SITAGLIPTIN/MYLAN TABLET, FILM COATED 100MG	9417/21T	023448	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
SITAGLIPTIN/MYLAN TABLET, FILM COATED 25MG	9415/21T	023446	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LOGNIF CAPSULE, HARD 0.5MG	2903/22T	023340	TEVA GMBH	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process

LAMIVUDINE/ZIDOVUDINE AUROBINDO TABLET, FILM COATED 150MG/300MG	2398/22T	023011	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RAMI-AMLO CAPSULE, HARD (10+5)MG	2254/22T	022125	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
RAMI-AMLO CAPSULE, HARD (10+10)MG	2255/22T	022127	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
RAMI-AMLO CAPSULE, HARD (5+10)MG	2253/22T	022126	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
RAMI-AMLO CAPSULE, HARD (5+5)MG	2252/22T	022124	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
GLUCOPHAGE TABLET, FILM COATED 850MG	6006/21T	020698	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 750MG	6003/21T	022948	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 1000MG	6004/21T	022949	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 500MG	6002/21T	022947	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE TABLET, FILM COATED 1000MG	6005/21T	020469	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GLUCOPHAGE TABLET, FILM COATED 500MG	6007/21T	020697	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
IRINOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	9678/21T	022453	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
RAPIBLOC POWDER FOR SOLUTION FOR INFUSION 300MG/VIAL	5807/21T	022744	AMOMED PHARMA GMBH.	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	7669/21T	20630	CSL BEHRING GMBH	B.II.b.2.a B.II.b.2.a - QUALITY

				CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	9420/21T, 9421/21T, 9422/21T	022345	BIOTEST PHARMA GMBH	B.II.d.2.e B.II.d.2.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur. B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product* B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 10MG	1600/22T, 1601/22T, 1602/22T, 1603/22T, 1604/22T, 1605/22T, 1606/22T, 1607/22T, 1608/22T, 1609/22T, 1610/22T, 1611/22T, 1612/22T, 1613/22T,	018077	NOVARTIS IRELAND LIMITED	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of

	1614/22T, 1615/22T, 1616/22T, 1617/22T, 1618/22T, 1619/22T, 1620/22T			excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.1.b B.II.c.1.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 30MG	1642/22T, 1643/22T, 1644/22T, 1645/22T, 1646/22T, 1647/22T, 1648/22T, 1649/22T, 1650/22T, 1651/22T, 1652/22T, 1653/22T, 1654/22T, 1655/22T, 1656/22T, 1657/22T, 1658/22T, 1659/22T, 1660/22T, 1661/22T, 1662/22T	018079	NOVARTIS IRELAND LIMITED	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.1.b B.II.c.1.b - QUALITY CHANGES - FINISHED

				PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 20MG	1621/22T, 1622/22T, 1623/22T, 1624/22T, 1625/22T, 1626/22T, 1627/22T, 1628/22T, 1629/22T, 1630/22T, 1631/22T, 1632/22T, 1633/22T, 1634/22T, 1635/22T, 1636/22T, 1637/22T, 1638/22T, 1639/22T, 1640/22T, 1641/22T	018078	NOVARTIS IRELAND LIMITED	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.1.b B.II.c.1.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the

				specification with its corresponding test method B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
ALSAMOD TABLET, FILM COATED 40MG/5MG	1897/22T	023344	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALSAMOD TABLET, FILM COATED 20MG/5MG	1895/22T	023343	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALSAMOD TABLET, FILM COATED 40MG/10MG	1896/22T	023345	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/VIAL(100IU/ML)	9656/21T	020944	OCTAPHARMA (IP) SPRL	B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/int

				ermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/VIAL (100IU/ML)	9655/21T	020943	OCTAPHARMA (IP) SPRL	B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance
GEMCITABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	531/21T, 532/21T	021481	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
RUPAFIN ORAL SOLUTION 1MG/ML	2769/22T	21571	J. URIACH Y COMPANIA S.A.	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site

				for part or all of the manufacturing process of the finished product - Secondary packaging site
ALSAMOD TABLET, FILM COATED 40MG/5MG	2413/22T	023344	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that

				require additional minor assessment, e.g. translations are not yet agreed upon
ALSAMOD TABLET, FILM COATED 20MG/5MG	2411/22T	023343	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional

				minor assessment, e.g. translations are not yet agreed upon
ALSAMOD TABLET, FILM COATED 40MG/10MG	2412/22T	023345	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment,

				e.g. translations are not yet agreed upon
REVAMOX TABLET, FILM COATED 200MG	3164/22T	023581	GENEPHARM SA	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
BORTEZOMIB/BAXTER POWDER FOR SOLUTION FOR INJECTION 3.5MG	1257/22T, 3055/22T	023553	BAXTER HOLDING B.V.	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
CURILEN CAPSULE, HARD 5MG/75MG	3229/22T	022988	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of

				pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
CURILEN CAPSULE, HARD 10MG/100MG	3232/22T	022991	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
CURILEN CAPSULE, HARD 5MG/100MG	3231/22T	022990	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
CURILEN CAPSULE, HARD 10MG/75MG	3230/22T	022989	UNI-PHARMA KLEON TSETIS PHARMACEU	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

			TICAL LABORATORIES SA	HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
BOSENTAN ACCORD TABLET, FILM COATED 125MG	1281/22T	022670	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BOSENTAN ACCORD TABLET, FILM COATED 62.5MG	1280/22T	022669	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosi

				milar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ANASTROZOLE ACCORD TABLET, FILM COATED 1MG	9155/21T, 9156/21T, 9157/21T	020488	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
LENALIDOMIDE GRINDEKS CAPSULE, HARD 10MG	7253/21T	023530	AS GRINDEKS	B.I.z B.I.z - Quality change - Active substance - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 20MG	7256/21T	023532	AS GRINDEKS	B.I.z B.I.z - Quality change - Active substance - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 15MG	7254/21T	023531	AS GRINDEKS	B.I.z B.I.z - Quality change - Active substance - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 25MG	7255/21T	023533	AS GRINDEKS	B.I.z B.I.z - Quality change - Active substance - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 7.5MG	7252/21T	023529	AS GRINDEKS	B.I.z B.I.z - Quality change -

				Active substance - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 5MG	7257/21T	023528	AS GRINDEKS	B.I.z B.I.z - Quality change - Active substance - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 2.5MG	7251/21T	023527	AS GRINDEKS	B.I.z B.I.z - Quality change - Active substance - Other variation
NEISVAC-C SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 10MCG/0.5ML	3550/22T	020480	PFIZER HELLAS AE	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
CONCERTA TABLET, PROLONGED-RELEASE 54MG	4606/21T	020336	JANSSEN-CILAG INTERNATIONAL NV	C.I.6.a C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one
CONCERTA TABLET, PROLONGED-RELEASE 36MG	4605/21T	020340	JANSSEN-CILAG INTERNATIONAL NV	C.I.6.a C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one
CONCERTA TABLET, PROLONGED-RELEASE 18MG	4604/21T	020339	JANSSEN-CILAG INTERNATIONAL NV	C.I.6.a C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one
VEDIDA POWDER FOR SOLUTION FOR INFUSION 200MG	2704/22T	023413	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	3319/22T	022372	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the

				assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	3320/22T	022371	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VAXIGRIPTETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	3371/22T	022512	SANOFI PASTEUR.	B.I.a.5.a B.I.a.5.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes to the active substance of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza
TORVACARD NEO TABLET, FILM COATED 20MG	1901/22T	022248	ZENTIVA K.S.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of the marketing authorisation holder
TORVACARD NEO TABLET, FILM COATED 80MG	1899/22T	022250	ZENTIVA K.S.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TORVACARD NEO TABLET, FILM COATED 40MG	1900/22T	022249	ZENTIVA K.S.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TORVACARD NEO TABLET, FILM COATED 10MG	1902/22T	022247	ZENTIVA K.S.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SIRANALEN CAPSULE, HARD 300MG	2879/22T	022532	MEDOCHE MIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SIRANALEN CAPSULE, HARD 150MG	2878/22T	022531	MEDOCHE MIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet

				intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
SIRANALEN CAPSULE, HARD 75MG	2877/22T	022530	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
VIMETSO TABLET, FILM COATED 50MG/850MG	2698/22T	023480	TAD PHARMA GMBH	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
VIMETSO TABLET, FILM COATED 50MG/1000MG	2699/22T	023481	TAD PHARMA GMBH	B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	3220/22T, 3221/22T, 3222/22T	020984	SANDOZ GMBH	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)

ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	3223/22T, 3224/22T, 3225/22T	020985	SANDOZ GMBH	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	3226/22T, 3227/22T, 3228/22T	020987	SANDOZ GMBH	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information B.II.e.2.c B.II.e.2.c - QUALITY

				CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
DEXMEDETOMIDINE/BAXTER CONCENTRATE FOR SOLUTION FOR INFUSION 100MCG/ML	1375/22T	023455	BAXTER HOLDING B.V.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	1290/22T, 1291/22T	022511	SANOFI PASTEUR.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
NEXIUM TABLET, GASTRO-RESISTANT 40MG	2515/22T	019421	C G PAPALOISO U LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
NEXIUM I.V. POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG	2516/22T	019788	C G PAPALOISO U LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g.

				agreed wording + template change)
NEXIUM GASTRO-RESISTANT GRANULES FOR ORAL SUSPENSION 10MG	2513/22T	020461	C G PAPALOISO U LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
NEXIUM TABLET, GASTRO-RESISTANT 20MG	2514/22T	019420	C G PAPALOISO U LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
LOMEXIN VAGINAL CAPSULE, SOFT 600MG	3739/22T	022897	RECORDAT I IRELAND LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LOMEXIN VAGINAL CAPSULE, SOFT 200MG	3738/22T	022896	RECORDATI IRELAND LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 10MG	2822/22T	018077	NOVARTIS IRELAND LIMITED	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active

				substance-replacement or addition of a site where batch control/testing takes place
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 30MG	2821/22T	018079	NOVARTIS IRELAND LIMITED	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 20MG	2820/22T	018078	NOVARTIS IRELAND LIMITED	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes

				to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place
SANDOSTATIN SOLUTION FOR INJECTION & INFUSION 0.1MG/ML	2819/22T	018418	NOVARTIS IRELAND LIMITED	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place
LIOTON 1000 GEL 100000IU/100G	8045/21T	013373	A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE SRL	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur.

				Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the
LAVIFENT PATCH, TRANSDERMAL 50MCG/HOUR	3689/22T	020840	LAVIPHARM A.E.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance

				System Master File (PSMF) location
LAVIFENT PATCH, TRANSDERMAL 100MCG/HOUR	3687/22T	020842	LAVIPHARM A.E.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
LAVIFENT PATCH, TRANSDERMAL 75MGG/HOUR	3688/22T	020841	LAVIPHARM A.E.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
LAVIFENT PATCH, TRANSDERMAL 25MCG/HOUR	3690/22T	020839	LAVIPHARM A.E.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of

				pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
NEPHROTECT SOLUTION FOR INFUSION 10%	9285/21T, 9286/21T, 9287/21T, 9288/21T, 9289/21T, 9290/21T	020261	FRESENIUS KABI HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile
FUSIDIC ACID/BETAMETHASONE VALERATE PHARMASCIENCE INTERNATIONAL CREAM (20MG/1MG)/G	3734/22T, 3735/22T	022726	PHARMASCIENCE INTERNATIONAL LTD	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100/12.5MG	9484/21T	020921	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

ARPOYA TABLET, ORODISPERSIBLE 30MG	3553/22T	022652	PHARMATHEN INTERNATIONAL S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ARPOYA TABLET, ORODISPERSIBLE 10MG	3551/22T	022650	PHARMATHEN INTERNATIONAL S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ARPOYA TABLET, ORODISPERSIBLE 15MG	3552/22T	022651	PHARMATHEN INTERNATIONAL S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	2546/22T	022345	BIOTEST PHARMA GMBH	B.I.e.2 B.I.e.2 - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Introduction of a post approval change management protocol related to the active substance
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU WITH 10ML SOLVENT	2245/22T, 2246/22T, 2247/22T	020331	BAXALTA INNOVATIONS GMBH	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a

				manufacturer of a novel excipient (where specified in the technical dossier) A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU WITH 10ML SOLVENT	2248/22T, 2249/22T, 2250/22T	020332	BAXALTA INNOVATIONS GMBH	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the

				manufacturer/importer is responsible do not include batch release
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250IU WITH 10ML SOLVENT	2242/22T, 2243/22T, 2244/22T	020330	BAXALTA INNOVATIONS GMBH	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
MEDICORT TABLET 8MG	2868/22T	023496	MEDICAIR BIOSCIENCE LABORATORIES CY LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
MEDICORT TABLET 4MG	2867/22T	023495	MEDICAIR BIOSCIENCE LABORATORIES CY LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
MEDICORT TABLET 20MG	2869/22T	023497	MEDICAIR BIOSCIENCE LABORATORIES CY LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
CORTIMENT TABLET, PROLONGED-RELEASE 9MG	2237/22T	022367	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SCABALL TABLET 3MG	3391/22T	023537	EPSILON HEALTH (NESTORAS VLACHOS P.C.)	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	302/22T, 303/22T	022372	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site

				where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	300/22T, 301/22T	022371	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
RIDOCA CAPSULE, HARD 100MG	2602/22T	022132	AENORASIS SA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RIDOCA CAPSULE, HARD 250MG	2605/22T	022135	AENORASIS SA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RIDOCA CAPSULE, HARD 140MG	2603/22T	022133	AENORASIS SA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosi

				milar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RIDOCA CAPSULE, HARD 20MG	2601/22T	022131	AENORASIS SA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RIDOCA CAPSULE, HARD 180MG	2604/22T	022134	AENORASIS SA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to

				be submitted by the MAH
RIDOCA CAPSULE, HARD 5MG	2600/22T	022130	AENORASIS SA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SEVOFLURANE-PIRAMAL INHALATION VAPOUR, LIQUID 100% V/V	835/22T	021303	PIRAMAL CRITICAL CARE B.V.	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
IRBESARTAN ACCORD TABLET, FILM COATED 150MG	2733/22T	021645	ACCORD HEALTHCARE S.L.U	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
ACLONIA TABLET 70MG/5600IU	9382/21T	022675	PHARMATHEN S.A.	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient

ACLONIA TABLET 70MG/2800IU	9381/21T	022674	PHARMATHEN S.A.	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
FINGOLIMOD PHARMASCIENCE CAPSULE, HARD 0.5MG	1289/22T	023482	PHARMASCIENCE INTERNATIONAL LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
IRITEC CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/5ML	8915/20T, 8916/20T	20648	VIANEX S.A	B.II.b.4 d) The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes B.II.b.3 a) Minor change in the manufacturing process
IRITEC CONCENTRATE FOR SOLUTION FOR INFUSION 40MG/2ML	8917/20T, 8918/20T	20647	VIANEX S.A	B.II.b.4 d) The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes B.II.b.3 a) Minor change in the manufacturing process
NOCDURNA ORAL LYOPHILISATE 25MCG	2693/22T	022543	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PROPESS VAGINAL DELIVERY SYSTEM 10MG/UNIT	2695/22T	022926	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
NOCDURNA ORAL LYOPHILISATE 50MCG	2694/22T	022544	FERRING HELLAS MEPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ACICLOVIR ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	4685/21T	023226	ACCORD HEALTHCARE S.L.U	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
LEVOSERT INTRA UTERINE SYSTEM 52MG (20MCG/24h)	5496/21T	022402	GEDEON RICHTER PLC	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
VERRIA TABLET, FILM COATED 200MG	1894/22T	022537	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VERRIA TABLET, FILM COATED 50MG	1893/22T	022536	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CIPRALEX TABLET, FILM COATED 15MG	7218/21T	020268	H.LUNDBECK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to

				implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
CIPRALEX TABLET, FILM COATED 20MG	7219/21T	020269	H.LUNDBECK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
CIPRALEX TABLET, FILM COATED 10MG	7217/21T	020267	H.LUNDBECK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment,

				e.g. translations are not yet agreed upon
CIPRALEX TABLET, FILM COATED 5MG	7216/21T	020266	H.LUNDBECK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
COMPRELAN TABLET, FILM COATED 40MG/10MG	2132/22T	023570	RAFARM S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
COMPRELAN TABLET, FILM COATED 40MG/5MG	2131/22T	023569	RAFARM S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
COMPRELAN TABLET, FILM COATED 20MG/5MG	2130/22T	023568	RAFARM S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
RAMI-AMLO CAPSULE, HARD (10+5)MG	2551/22T, 2552/22T	022125	IASIS PHARMACEUTICALS HELLAS SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* -

				Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
RAMI-AMLO CAPSULE, HARD (10+10)MG	2553/22T, 2554/22T	022127	IASIS PHARMACEUTICALS HELLAS SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
RAMI-AMLO CAPSULE, HARD (5+10)MG	2549/22T, 2550/22T	022126	IASIS PHARMACEUTICALS HELLAS SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or

				changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
RAMI-AMLO CAPSULE, HARD (5+5)MG	2547/22T, 2548/22T	022124	IASIS PHARMACEUTICALS HELLAS SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
ANAGRELIDE AOP CAPSULE, HARD 0.5MG	3105/22T, 3106/22T	023145	AOP ORPHAN PHARMACEUTICALS GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure

ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	2734/22T, 2735/22T, 2736/22T	022396	SANOFI PASTEUR.	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	2779/22T, 2780/22T	020206	GRIFOLS DEUTSCHLAND GMBH.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/320MG/25MG	7295/21T	023351	ELPEN PHARMACEUTICAL CO INC	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/160MG/25MG	7294/21T	023350	ELPEN PHARMACEUTICAL CO INC	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 5MG/160MG/12.5MG	7296/21T	023349	ELPEN PHARMACEUTICAL CO INC	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
N-ACETYLCYSTEINE SANDOZ ORAL POWDER 600MG IN SACHETS	499/22T	null	SANDOZ GMBH	C.I.13 C.I.13 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variations not specifically covered elsewhere in this Annex which

				involve the submission of studies to the competent authority
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	9559/21T	019161	SANOFI-AVENTIS GROUPE	B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	9557/21T	019160	SANOFI-AVENTIS GROUPE	B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	9556/21T	019159	SANOFI-AVENTIS GROUPE	B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	9558/21T	019744	SANOFI-AVENTIS GROUPE	B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	7492/21T	019161	SANOFI-AVENTIS GROUPE	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	7490/21T	019160	SANOFI-AVENTIS GROUPE	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	7489/21T	019159	SANOFI-AVENTIS GROUPE	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the

				active substance - Other changes
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	7491/21T	019744	SANOFI-AVENTIS GROUPE	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
NUROFEN DURANCE MEDICATED PLASTER 200MG	7174/21T	022903	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DUODART CAPSULE, HARD	2560/22T	020719	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSUVASTATIN/MYLAN TABLET, FILM COATED 10MG	2415/22T	022929	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the

				(invented) name of the medicinal product - for Nationally Authorised Products
ROSUVASTATIN/MYLAN TABLET, FILM COATED 5MG	2414/22T	022928	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ROSUVASTATIN/MYLAN TABLET, FILM COATED 20MG	2416/22T	022930	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
VALGANCICLOVIR AUROBINDO TABLET, FILM COATED 450MG	3556/21T	022358	AUROBINDO PHARMA (MALTA) LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
TAFLOTAN EYE DROPS, SOLUTION 15MCG/ML	4021/21T, 4022/21T, 4023/21T	022835	VIANEX S.A	B.II.e.5.c B.II.e.5.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/ immunological medicinal products B.II.f.1.b.2 B.II.f.1.b.2 -

				QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - After first opening (supported by real time data)
MELPHALAN TILLOMED POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 50MG/VIAL	2408/22T	022629	TILLOMED PHARMA GMBH.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ROPIVACAINE KABI SOLUTION FOR INFUSION 2MG/ML	9519/21T	021422	FRESENIUS KABI HELLAS A.E.	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
PROCTO-GLYVENOL RECTAL CREAM	7406/21T, 7407/21T	017441	RECORDATI HELLAS PHARMACEUTICALS SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in

				the holding time of an intermediate B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
SANDOSTATIN SOLUTION FOR INJECTION & INFUSION 0.1MG/ML	3042/22T, 3043/22T, 3044/22T, 3045/22T	018418	NOVARTIS IRELAND LIMITED	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
AUGMENTIN TABLET, FILM COATED 500MG/125MG	3749/21T	012656	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEISVAC-C SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 10MCG/0.5ML	2423/22T, 2424/22T	020480	PFIZER HELLAS AE	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.b.1.f B.I.b.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Change outside the approved specifications limits range for the active substance
SMOFKABIVEN EXTRA NITROGEN EMULSION FOR INFUSION	9597/21T, 9598/21T, 9599/21T, 9600/21T, 9601/21T, 9602/21T,	023282	FRESENIUS KABI HELLAS AE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES -

	9603/21T, 9604/21T, 9605/21T			ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
SMOFKABIVEN LOW OSMO PERIPHERAL EMULSION FOR INFUSION	9579/21T, 9580/21T, 9581/21T, 9582/21T, 9583/21T, 9584/21T, 9585/21T, 9586/21T, 9587/21T	023281	FRESENIUS KABI HELLAS AE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance -

				Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION	9588/21T, 9589/21T, 9590/21T, 9591/21T, 9592/21T, 9593/21T, 9594/21T, 9595/21T, 9596/21T	20667	FRESENIUS KABI HELLAS AE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active

				substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
SMOFKABIVEN EMULSION FOR INFUSION	9606/21T, 9607/21T, 9608/21T, 9609/21T, 9610/21T, 9611/21T, 9612/21T, 9613/21T, 9614/21T	20651	FRESENIUS KABI HELLAS AE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the

				manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
OLMESARTAN TAD TABLET, FILM COATED 10MG	1376/22T	022821	TAD PHARMA GMBH	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
OLMESARTAN TAD TABLET, FILM COATED 40MG	1378/22T	022823	TAD PHARMA GMBH	B.II.b.5.z B.II.b.5.z - QUALITY

				CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
OLMESARTAN TAD TABLET, FILM COATED 20MG	1377/22T	022822	TAD PHARMA GMBH	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Minor change of an analytical procedure for an in-process control
SOOLANTRA CREAM 10MG/G	9439/21T	022320	GALDERMA INTERNATIONAL,FRANCE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ABSTRAL TABLET, SUBLINGUAL 600MCG	700/22T	020608	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ABSTRAL TABLET, SUBLINGUAL 100MCG	696/22T	020604	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

ABSTRAL TABLET, SUBLINGUAL 300MCG	698/22T	020606	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ABSTRAL TABLET, SUBLINGUAL 200MCG	697/22T	20605	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of

				wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ABSTRAL TABLET, SUBLINGUAL 400MCG	699/22T	020607	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ABSTRAL TABLET, SUBLINGUAL 800MCG	701/22T	020609	KYOWA KIRIN HOLDINGS B.V.	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the

				outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
LEVOXACIN TABLET, FILM COATED 500MG	2665/22T	020748	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
LEVOXACIN TABLET, FILM COATED 250MG	2664/22T	020747	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
TRIACOR TABLET, PROLONGED-RELEASE 5MG/5MG	8952/20T, 8953/20T	019492	SANOFI-AVENTIS GROUPE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
VOLULYTE SOLUTION FOR INFUSION 6%	2427/22T	20656	FRESENIUS KABI DEUTSCHLAND GMBH, GERMANY	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NOSATEL SOLUTION FOR INJECTION OR INFUSION 50MG/2ML	6300/21T, 6301/21T, 6302/21T, 6303/21T, 6304/21T, 6305/21T, 6306/21T, 6307/21T	020155	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.a B.II.d.2.a

				- QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
FOSRENOL TABLET, CHEWABLE 750MG	860/22T	020047	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FOSRENOL TABLET, CHEWABLE 500MG	859/22T	020046	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
NEPHROTECT SOLUTION FOR INFUSION 10%	1739/22T	020261	FRESENIUS KABI HELLAS AE	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
ARIMIDEX TABLET, FILM COATED 1MG	970/22T	017100	LABORATOIRES JUVISE PHARMACEUTICALS	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location

CERTICAN TABLET 0.75MG	9653/21T	019644	NOVARTIS IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
CERTICAN TABLET 0.5MG	9652/21T	019643	NOVARTIS IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
CERTICAN TABLET 0.25MG	9651/21T	019642	NOVARTIS IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
CERTICAN TABLET 1MG	9654/21T	019645	NOVARTIS IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
CERTICAN TABLET 0.75MG	9214/21T	019644	NOVARTIS IRELAND LIMITED	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
CERTICAN TABLET 0.5MG	9213/21T	019643	NOVARTIS IRELAND LIMITED	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
CERTICAN TABLET 0.25MG	9212/21T	019642	NOVARTIS IRELAND LIMITED	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
CERTICAN TABLET 1MG	9215/21T	019645	NOVARTIS IRELAND LIMITED	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes

CERTICAN TABLET 0.75MG	8194/21T	019644	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
CERTICAN TABLET 0.5MG	8193/21T	019643	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
CERTICAN TABLET 1MG	8195/21T	019645	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
CERTICAN TABLET 0.25MG	8192/21T	019642	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the

				manufacturer/importer is responsible do not include batch release
CERTICAN TABLET 0.75MG	3734/21T	019644	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
CERTICAN TABLET 0.5MG	3736/21T	019643	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
CERTICAN TABLET 0.25MG	3733/21T	019642	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing

CERTICAN TABLET 1MG	3735/21T	019645	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
VORICONAZOLE FRESENIUS KABI POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	9163/21T, 9164/21T, 9165/21T	022460	FRESENIUS KABI HELLAS A.E.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SOLPADEINE COLD & FLU CAPSULE, HARD 500MG/100MG/6.1MG	1748/22T	023546	OMEGA PHARMA HELLAS S.A	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place

ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 40MG	7123/21T	020971	KRKA D.D. NOVO MESTO	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 20MG	7122/21T	020970	KRKA D.D. NOVO MESTO	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ZYRTEC ORAL SOLUTION 0.1%	843/22T	016365	UCB PHARMA SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZYRTEC TABLET, FILM COATED 10MG	842/22T	013066	UCB PHARMA SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DINAPLEX CAPSULE, HARD 0.5MG/0.4MG	3092/22T, 3093/22T	023119	ELPEN PHARMACEUTICAL CO INC	B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - New certificate for a starting

				material/reagent/ intermediate/or excipient from a new or an already approved manufacturer
MYCOPHENOLATE MOFETIL ACCORD TABLET, FILM COATED 500MG	1928/22T	020500	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
GLUCOSE 5%/BAXTER (VIAFLO) SOLUTION FOR INFUSION 5% W/V	1956/22T	019767	BAXTER (HELLAS) EPE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LOSEC MUPS TABLET, GASTRO-RESISTANT 20MG	4888/21T	018064	CHEPLAPHARM ARZNEIMITTEL GMBH.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data
LOSEC MUPS TABLET, GASTRO-RESISTANT 10MG	4887/21T	018063	CHEPLAPHARM ARZNEIMITTEL GMBH.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SYMBICORT TURBUHALER POWDER FOR INHALATION 320MCG/9MCG	793/22T	020882	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5MCG	796/22T	020883	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL XR TABLET, PROLONGED-RELEASE 200MG	785/22T	020357	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SYMBICORT PRESSURISED INHALATION, SUSPENSION 160/4.5MCG/ACTUATION	782/22T	022403	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	792/22T	020881	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL TABLET, FILM COATED 200MG	791/22T	017718	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
SEROQUEL TABLET, FILM COATED 100MG	790/22T	017717	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL TABLET, FILM COATED 25MG	789/22T	017716	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SYMBICORT PRESSURISED INHALATION, SUSPENSION 80MCG/2.25MCG/ACTUATION	783/22T	023164	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PLENDIL TABLET, PROLONGED-RELEASE 10MG	795/22T	012025	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PLENDIL TABLET, PROLONGED-RELEASE 5MG	794/22T	012026	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL XR TABLET, PROLONGED-RELEASE 150MG	788/22T	020699	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL XR TABLET, PROLONGED-RELEASE 400MG	787/22T	020359	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SEROQUEL XR TABLET, PROLONGED-RELEASE 300MG	786/22T	020358	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

SEROQUEL XR TABLET, PROLONGED-RELEASE 50MG	784/22T	020356	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 50U	2525/22T	023325	MERZ PHARMACEUTICALS GMBH	B.II.b.3.c B.II.b.3.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 100U	2526/22T	023324	MERZ PHARMACEUTICALS GMBH	B.II.b.3.c B.II.b.3.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability
ALPRAZOLAM TAD TABLET 0.5MG	6509/21T	023244	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
ALPRAZOLAM TAD TABLET 1MG	6510/21T	023245	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference

				product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
ALPRAZOLAM TAD TABLET 0.25MG	6508/21T	023243	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b -

				SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
OLIMEL N7E EMULSION FOR INFUSION	754/22T	022010	BAXTER (HELLAS) EPE	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not

				claimed to be endotoxin free
OLIMEL N12E EMULSION FOR INFUSION	756/22T	023257	BAXTER (HELLAS) EPE	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
OLIMEL N9E EMULSION FOR INFUSION	755/22T	022011	BAXTER (HELLAS) EPE	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New

				certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
OLIMEL PERI N4E EMULSION FOR INFUSION	753/22T	022008	BAXTER (HELLAS) EPE	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	839/22T	020201	BAXALTA INNOVATIONS GMBH	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a

				change for a biological/immunological medicinal product
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	838/22T	020200	BAXALTA INNOVATIONS GMBH	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	837/22T	020199	BAXALTA INNOVATIONS GMBH	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product
DIOVAN ORAL SOLUTION 3MG/ML	2425/22T, 2426/22T	020694	NOVARTIS IRELAND LIMITED	B.II.e.1.a.2 B.II.e.1.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED

				PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
GRAFALON CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	1847/22T, 1848/22T, 1849/22T	017186	NEOVII BIOTECH GMBH	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.I.b.1.a B.I.b.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits for medicinal products subject to Official Control Authority Batch Release B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits
THYROFIX TABLET 62MCG	2893/22T	022998	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active

			LABORATORIES SA	substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 200MCG	2902/22T	023005	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 100MCG	2896/22T	022243	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 125MCG	2898/22T	023001	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 13MCG	2890/22T	022997	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 150MCG	2900/22T	023003	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 175MCG	2901/22T	023004	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 137MCG	2899/22T	023002	UNI-PHARMA	A.7 A.7 - ADMINISTRATIVE

			KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 88MCG	2895/22T	022999	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 112MCG	2897/22T	023000	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 50MCG	2892/22T	022241	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site,

				manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 75MCG	2894/22T	022242	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
THYROFIX TABLET 25MCG	2891/22T	022240	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
APIXABAN/MYLAN TABLET, FILM COATED 5MG	1570/22T, 1571/22T	023470	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products

APIXABAN/MYLAN TABLET, FILM COATED 2.5MG	1572/22T, 1573/22T	023469	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
SIRANALEN CAPSULE, HARD 300MG	340/22T	022532	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SIRANALEN CAPSULE, HARD 150MG	339/22T	022531	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended

				to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SIRANALEN CAPSULE, HARD 75MG	338/22T	022530	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	183/22T, 184/22T, 185/22T, 186/22T, 187/22T	022401	ALLERGAN PHARMACEUTICALS IRELAND	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product.

				(PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	178/22T, 179/22T, 180/22T, 181/22T, 182/22T	022400	ALLERGAN PHARMACEUTICALS IRELAND	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	173/22T, 174/22T, 175/22T, 176/22T, 177/22T	022399	ALLERGAN PHARMACEUTICALS IRELAND	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	168/22T, 169/22T, 170/22T, 171/22T, 172/22T	020032	ALLERGAN PHARMACEU	B.V.a.1.d B.V.a.1.d - QUALITY

			TICALS IRELAND	CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	168/22T, 169/22T, 170/22T, 171/22T, 172/22T	020032	ALLERGAN PHARMACEUTICALS IRELAND	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
RUPAFIN ORAL SOLUTION 1MG/ML	7557/21T	21571	J. URIACH Y COMPANIA S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TADALAFIL SANDOZ TABLET, FILM COATED 20MG	1166/22T	022668	SANDOZ GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
TADALAFIL SANDOZ TABLET, FILM COATED 5MG	1165/22T	022667	SANDOZ GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
DELAZO EYE DROPS, SOLUTION 20MG/ML	1948/22T	023180	PHARMATHEN S.A.	B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes
BUSCOFEM CAPSULE, SOFT 400MG	2469/22T	022424	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible

				include batch release
BUFAR EASYHALER POWDER FOR INHALATION 80MCG/4.5MCG/INHALATION	2135/22T, 2136/22T	022432	ORION CORPORATION (ORION PHARMA)	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PRAGIOLA CAPSULE, HARD 75MG	2061/22T	022689	KRKA D.D. NOVO MESTO	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes

PRAGIOLA CAPSULE, HARD 150MG	2062/22T	022690	KRKA D.D. NOVO MESTO	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
DYMISTA NASAL SPRAY, SUSPENSION	1750/22T	021885	MEDA PHARMACEUTICALS S.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
LINEZOLID ACCORD SOLUTION FOR INFUSION 2MG/ML	2845/21T, 2846/21T, 2847/21T, 2848/21T, 2849/21T	022785	ACCORD HEALTHCARE S.L.U	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing

				process of the active substance - Minor changes to an approved test procedure
ORATORIA EYE DROPS, SOLUTION 1MG/ML	1975/22T	023179	PHARMATHEN S.A.	B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes
ALENDRONIC ACID AUROBINDO TABLET 70MG	1941/22T	023246	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TORVACARD TABLET, FILM COATED 20MG	9324/21T	020931	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following

				assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TORVACARD TABLET, FILM COATED 10MG	9325/21T	020930	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TORVACARD TABLET, FILM COATED 40MG	9323/21T	020932	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

TORVACARD TABLET, FILM COATED 80MG	9322/21T	020933	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
XYZAL TABLET, FILM COATED 5MG	2034/22T, 2035/22T, 2036/22T	020044	UCB PHARMA SA	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure

CREON 10000 CAPSULE, HARD 150MG	5917/21T	018755	MYLAN IRE HEALTHCAR E LIMITED	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
MYCOPHENOLATE MOFETIL ACCORD CAPSULE, HARD 250MG	1788/22T	020915	ACCORD HEALTHCAR E S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 360MG	2009/22T	022405	ACCORD HEALTHCAR E S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 180MG	2008/22T	022404	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SITAGLIPTIN/MYLAN TABLET, FILM COATED 100MG	7793/21T, 7794/21T	023448	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally

				Authorised Products
SITAGLIPTIN/MYLAN TABLET, FILM COATED 25MG	7789/21T, 7790/21T	023446	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	7791/21T, 7792/21T	023447	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
KIVIZIDIALE EYE DROPS, SOLUTION (40MCG/5MG)/ML	316/22T	023220	BAUSCH + LOMB IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
DEXAMETHASONE PHOSPHATE NORIDEM SOLUTION FOR INJECTION 4MG/ML	2461/22T	023415	NORIDEM ENTERPRISES LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
NUROFEN LIQUID CAPSULE, SOFT 200MG	551/22T	020918	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

LEVOTHYROXINE ACCORD TABLET 25MCG	1288/21T	023138	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
LEVOTHYROXINE ACCORD TABLET 100MCG	1289/21T	023140	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
LEVOTHYROXINE ACCORD TABLET 50MCG	1290/21T	023139	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a

				generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
LEVIDE TABLET 100MG	2375/21T	022325	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
LEVIDE TABLET 25MG	2373/21T	022323	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
LEVIDE TABLET 50MG	2374/21T	022324	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
INTRATECT SOLUTION FOR INFUSION 100G/L	8341/21T	022263	BIOTEST PHARMA GMBH	B.I.b.1.f B.I.b.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting

				material / intermediate / reagent used in the manufacturing process of the active substance - Change outside the approved specifications limits range for the active substance
ROSU-ASA CAPSULE, HARD 5MG/100MG	450/22T, 451/22T	023199	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
ROSU-ASA CAPSULE, HARD 10MG/100MG	452/22T, 453/22T	023200	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
ROSU-ASA CAPSULE, HARD 20MG/100MG	454/22T, 455/22T	023201	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed

				upon A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
TOBRADEX EYE OINTMENT	8976/21T	017323	NOVARTIS IRELAND LIMITED	C.I.13 C.I.13 - C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - Submission of additional clinical and non-clinical studies, including BE-studies.
TOBREX EYE OINTMENT 0.3% W/W	8977/21T	017321	NOVARTIS IRELAND LIMITED	C.I.13 C.I.13 - C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - Submission of additional clinical and non-clinical studies, including BE-studies.
TOPAMAX SPRINKLES CAPSULE, HARD 25MG	750/22T	019576	JANSSEN-CILAG INTERNATIONAL NV	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TOPAMAX SPRINKLES CAPSULE, HARD 15MG	749/22T	019558	JANSSEN-CILAG INTERNATIONAL NV	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data

TOPAMAX TABLET, FILM COATED 200MG	748/22T	018278	JANSSEN-CILAG INTERNATIONAL NV	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TOPAMAX TABLET, FILM COATED 25MG	745/22T	018277	JANSSEN-CILAG INTERNATIONAL NV	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TOPAMAX TABLET, FILM COATED 50MG	746/22T	018276	JANSSEN-CILAG INTERNATIONAL NV	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TOPAMAX TABLET, FILM COATED 100MG	747/22T	018275	JANSSEN-CILAG INTERNATIONAL NV	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TOPAMAX SPRINKLES CAPSULE, HARD 50MG	751/22T	019557	JANSSEN-CILAG INTERNATIONAL NV	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 5/160/12.5MG	3050/22T	023475	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE	3048/22T	023479	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY,

MYLAN PHARMA TABLET, FILM COATED 10/320/25MG				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/160/25MG	3047/22T	023478	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 10/160/12.5MG	3046/22T	023477	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE MYLAN PHARMA TABLET, FILM COATED 5/160/25MG	3049/22T	023476	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ALENDRONIC ACID ACCORD TABLET 70MG	64/22T, 65/22T	020928	ACCORD HEALTHCARE S.L.U	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance -

				Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
REMODULIN SOLUTION FOR INFUSION 10MG/ML	9335/21T	020275	FERRER INTERNACIONAL S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
REMODULIN SOLUTION FOR INFUSION 1MG/ML	9332/21T	020272	FERRER INTERNACIONAL S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation,

				including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
REMODULIN SOLUTION FOR INFUSION 5MG/ML	9334/21T	020274	FERRER INTERNACIONAL S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
REMODULIN SOLUTION FOR INFUSION 2.5MG/ML	9333/21T	020273	FERRER INTERNACIONAL S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
VILDAGLIPTIN PHARMATHEN TABLET 50MG	8529/21T, 8530/21T, 8531/21T, 8532/21T	023063	PHARMATHEN S.A.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or

				changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
VAXIGRIPTETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	1955/22T	022512	SANOFI PASTEUR.	B.II.c.1.z B.II.c.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Other changes
DUROGESIC PATCH, TRANSDERMAL 100MCG/H	2522/22T	017987	JANSSEN-CILAG INTERNATIONAL NV	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
DUROGESIC PATCH, TRANSDERMAL 50MCG/H	2521/22T	017986	JANSSEN-CILAG INTERNATIONAL NV	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
DUROGESIC PATCH, TRANSDERMAL 25MCG/H	2520/22T	017985	JANSSEN-CILAG INTERNATIONAL NV	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
UNIDROPS EYE DROPS, SOLUTION 20MG/ML	7991/21T	022708	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance,

			LABORATORIES SA	intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DELAZO EYE DROPS, SOLUTION 20MG/ML	9443/21T, 9444/21T	023180	PHARMATHEN S.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
XALATAN EYE DROPS, SOLUTION 50MCG/ML	2823/22T, 2824/22T	020805	UPJOHN HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where

				specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
FEIBA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 25U/ML	153/22T, 154/22T, 155/22T, 156/22T, 157/22T	022343	BAXALTA INNOVATIONS GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the

				name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FEIBA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 50U/ML	158/22T, 159/22T, 160/22T, 161/22T, 162/22T	022344	BAXALTA INNOVATIONS GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or

				intermediate use A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
IMMUNATE 500 IU FVIII/375 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/5ML	143/22T, 144/22T, 145/22T, 146/22T, 147/22T	020085	BAXALTA INNOVATIONS GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

IMMUNATE 250 IU FVIII/190 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250IU/5ML	138/22T, 139/22T, 140/22T, 141/22T, 142/22T	020084	BAXALTA INNOVATIONS GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
IMMUNATE 1000 IU FVIII/750 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/10ML	148/22T, 149/22T, 150/22T, 151/22T, 152/22T	020086	BAXALTA INNOVATIONS GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer

				responsible for batch release, site where batch control takes place, or supplier of a starting A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLIFT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	7992/21T	022666	MYLAN IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the

				outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
BORTEZOMIB STADA SOLUTION FOR INJECTION 2.5MG/ML	7544/21T	023431	STADA ARZNEIMITTEL AG	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
ORIZAL PLUS TABLET, FILM COATED 40/10/12.5MG	7554/21T	021494	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	7553/21T	021493	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation,

				including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	7556/21T	021496	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	7552/21T	021492	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	7555/21T	021495	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g.

				agreed wording + template change)
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	6708/21T	20630	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUREX 5 SOLUTION FOR INFUSION 50G/L	6707/21T	20629	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	2057/22T	017527	GLAXOSMITHKLINE BIOLOGICALS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Updated certificate from an already approved manufacturer
ORIZAL TABLET, FILM COATED 40MG/5MG	5570/21T, 5571/21T	020613	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes B.II.a.3.b.6 B.II.a.3.b.6 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level
ORIZAL TABLET, FILM COATED 40MG/10MG	5572/21T, 5573/21T	020614	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the

				manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes B.II.a.3.b.6 B.II.a.3.b.6 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level
ORIZAL TABLET, FILM COATED 20MG/5MG	5574/21T, 5575/21T	020612	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes B.II.a.3.b.6 B.II.a.3.b.6 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level

URSOFALK ORAL SUSPENSION 250MG/5ML	6564/21T, 6565/21T, 6566/21T, 6567/21T, 6568/21T, 6569/21T, 6570/21T, 6571/21T, 6572/21T, 6573/21T	020790	DR. FALK PHARMA GMBH	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement B.II.d.2.f B.II.d.2.f - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - To reflect compliance with the Ph.Eur. and remove referen B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
SODIUM CHLORIDE/BAXTER(VIAFLO) SOLUTION FOR INFUSION 0.9% W/V	1960/22T	020065	BAXTER (HELLAS) EPE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Other variation
TOLTERODINE ACCORD TABLET, FILM COATED 2MG	6091/21T	020875	ACCORD HEALTHCARE S.L.U	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
VAXIGRIPTETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	8602/21T	022512	SANOFI PASTEUR.	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
ROPIVACAINE KABI SOLUTION FOR INJECTION 10MG/ML	9829/21T	021425	FRESENIUS KABI HELLAS A.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a

				Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
ROPIVACAINE KABI SOLUTION FOR INJECTION 7.5MG/ML	9828/21T	021424	FRESENIUS KABI HELLAS A.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
ROPIVACAINE KABI SOLUTION FOR INJECTION 5MG/ML	9827/21T	021423	FRESENIUS KABI HELLAS A.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety

				Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
ROPIVACAINE KABI SOLUTION FOR INFUSION 2MG/ML	9826/21T	021422	FRESENIUS KABI HELLAS A.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
ROPIVACAINE KABI SOLUTION FOR INJECTION 2MG/ML	9830/21T	021421	FRESENIUS KABI HELLAS A.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent

				authority that require additional minor assessment, e.g. translations are not yet agreed upon.
MONOPROST EYE DROPS, SOLUTION 50MCG/ML	828/22T, 829/22T, 830/22T	022828	LABORATOIRES THEA	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the

				manufacturing process of the active substance
MONOPROST EYE DROPS, SOLUTION IN SINGLE DOSE CONTAINER 50MCG/ML	831/22T, 832/22T, 833/22T	021947	LABORATO IRES THEA	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance

MONOPROST EYE DROPS, SOLUTION IN SINGLE DOSE CONTAINER 50MCG/ML	8383/21T, 8384/21T	021947	LABORATORIES THEA	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
GAVISCON STRAWBERRY FLAVOUR TABLET, CHEWABLE	9721/21T	022395	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GAVISCON LIQUID SACHETS	9720/21T	021163	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site

				where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GAVISCON PEPPERMINT TABLET, CHEWABLE	9722/21T	021162	RECKITT BENCKISER HELLAS HEALTHCAR E SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	7799/21T	021778	IBSA FARMACEUT ICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	7802/21T	020234	IBSA FARMACEUT ICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	7801/21T	020233	IBSA FARMACEUT ICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an

				excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	7800/21T	021777	IBSA FARMACEUTICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 225IU	7803/21T	021853	IBSA FARMACEUTICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 300IU	7804/21T	021854	IBSA FARMACEUTICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
VEDFA TABLET, FILM COATED 50MG/850MG	8537/21T, 8538/21T, 8539/21T, 8540/21T, 8541/21T	023389	PHARMATHEN S.A.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance

				system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
VEDFA TABLET, FILM COATED 50MG/1000MG	8542/21T, 8543/21T, 8544/21T, 8545/21T, 8546/21T	023390	PHARMATHEN S.A.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	744/22T	023239	SANOFI PASTEUR.	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the

				manufacturing process of the active substance - Other changes
ORIZAL PLUS TABLET, FILM COATED 40/10/12.5MG	6999/21T	021494	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	7000/21T	021493	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	6998/21T	021496	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification

				parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	7001/21T	021492	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	7002/21T	021495	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	1905/22T	020968	IPSEN PHARMA	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for

				importation and/or batch release - Not including batch control/testing
ALBUMAN SOLUTION FOR INFUSION 200G/L	1804/22T	023242	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUMAN SOLUTION FOR INFUSION 40G/L	1803/22T	023241	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	628/22T, 629/22T	022522	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or

				finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
CAMPTO CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	9440/21T	019188	PFIZER HELLAS AE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	707/22T	020201	BAXALTA INNOVATIONS GMBH	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	706/22T	020200	BAXALTA INNOVATIONS GMBH	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	705/22T	020199	BAXALTA INNOVATIONS GMBH	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
MYELOMIDE CAPSULE, HARD 5MG	2700/22T	023182	ANABIOSIS PC.	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
MYELOMIDE CAPSULE, HARD 10MG	2701/22T	023183	ANABIOSIS PC.	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure

MYELOMIDE CAPSULE, HARD 25MG	2703/22T	023185	ANABIOSIS PC.	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
MYELOMIDE CAPSULE, HARD 15MG	2702/22T	023184	ANABIOSIS PC.	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PROGRAF CAPSULE, HARD 0.5MG	2161/22T, 2162/22T	022365	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PROGRAF CAPSULE, HARD 1MG	2163/22T, 2164/22T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	2167/22T, 2168/22T	019080	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished

				product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PROGRAF CAPSULE, HARD 5MG	2165/22T, 2166/22T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MECOLZINE TABLET, GASTRO-RESISTANT 1000MG	1953/22T	023468	FAES FARMA SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
MECOLZINE TABLET, GASTRO-RESISTANT 500MG	1952/22T	023332	FAES FARMA SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
MECOLZINE TABLET, GASTRO-RESISTANT 500MG	1952/22T	023332	FAES FARMA SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
DINAPLEX CAPSULE, HARD 0.5MG/0.4MG	2055/22T	023119	ELPEN PHARMACEU	B.III.1.a.2 B.III.1.a.2 - QUALITY

			TICAL CO INC	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	3558/21T	022522	ACCORD HEALTHCARE S.L.U	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
METHOTREXATE ACCORD SOLUTION FOR INJECTION 25MG/ML	871/22T, 872/22T	021631	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for

				batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
VEDIDA POWDER FOR SOLUTION FOR INFUSION 200MG	743/22T	023413	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	8891/21T	023149	ACCORD HEALTHCARE S.L.U	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU

				Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	8892/21T	023150	ACCORD HEALTHCARE S.L.U	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	8890/21T	023148	ACCORD HEALTHCARE S.L.U	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	8893/21T	023151	ACCORD HEALTHCARE S.L.U	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully

				comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
LACOSAMIDE/GENEPHARM TABLET, FILM COATED 150MG	1889/22T	023117	GENEPHARM SA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LACOSAMIDE/GENEPHARM TABLET, FILM COATED 100MG	1888/22T	023116	GENEPHARM SA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LACOSAMIDE/GENEPHARM TABLET, FILM COATED 50MG	1887/22T	023115	GENEPHARM SA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LACOSAMIDE/GENEPHARM TABLET, FILM COATED 200MG	1890/22T	023118	GENEPHARM SA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
KIVIZIDIALE EYE DROPS, SOLUTION (40MCG/5MG)/ML	5752/21T, 5753/21T	023220	BAUSCH + LOMB IRELAND LIMITED	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstitute

				d product B.II.f.1.a.1 B.II.f.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Reduction of the shelf life of the finished product - As packaged for sale
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	4765/21T	022522	ACCORD HEALTHCARE S.L.U	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template) C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
FOSTIMON PFS POWDER AND SOLVENT FOR	2141/22T	021853	IBSA FARMACEUT	A.1 A.1 - ADMINISTRATIVE CHANGES -

SOLUTION FOR INJECTION 225IU			ICI ITALIA SRL	Change in the name and/or address of the marketing authorisation holder
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	2139/22T	021778	IBSA FARMACEUTICI ITALIA SRL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	2144/22T	020234	IBSA FARMACEUTICI ITALIA SRL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	2143/22T	020233	IBSA FARMACEUTICI ITALIA SRL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	2140/22T	021777	IBSA FARMACEUTICI ITALIA SRL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 300IU	2142/22T	021854	IBSA FARMACEUTICI ITALIA SRL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BILENI NASAL SPRAY, SUSPENSION	1749/22T	021884	MEDA PHARMACEUTICALS S.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
PULMOZYME NEBULISER SOLUTION 2500U/2.5ML	8314/21T	023074	ROCHE (HELLAS) SA	B.II.b.2.b B.II.b.2.b -

				QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method
SCABALL TABLET 3MG	72/22T, 73/22T, 74/22T, 75/22T	023537	EPSILON HEALTH (NESTORAS VLACHOS P.C.)	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product
TEMELOR TABLET 2.5MG	1057/22T	023629	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

TEMELOR TABLET 0.5MG	1055/22T	023627	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TEMELOR TABLET 1MG	1056/22T	023628	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DEXMEDETOMIDINE/KABI CONCENTRATE FOR SOLUTION FOR INFUSION 100MCG/ML	922/22T	023551	FRESENIUS KABI HELLAS AE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MENTIFAR TABLET, FILM COATED 20MG	9629/20T	022205	RAFARM S.A.	B.I z) ACTIVE SUBSTANCE Other variation
MENTIFAR TABLET, FILM COATED 10MG	9630/20T	022204	RAFARM S.A.	B.I z) ACTIVE SUBSTANCE Other variation
[18F]FDG/BIOKOSMOS SOLUTION FOR INJECTION 44-6.937MBq/ML	8252/20T	023102	BIOKOSMOS S.A.	B.I z) ACTIVE SUBSTANCE Other variation
CARAMLO TABLET 5MG/8MG	1746/22T	022063	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CARAMLO TABLET 10MG/16MG	1747/22T	022064	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AUGMENTIN MIXED FRUIT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	1668/22T	022824	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AUGMENTIN ES POWDER FOR ORAL SUSPENSION (600+42.9)MG/5ML	1666/22T	020148	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AUGMENTIN TABLET, FILM COATED 500MG/125MG	1667/22T	012656	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AUGMENTIN POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	1670/22T	019702	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AUGMENTIN TABLET, FILM COATED 1G	1669/22T	019515	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TICABRIL TABLET, FILM COATED 60MG	5043/21T	023300	TAD PHARMA GMBH	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by th C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by th C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s)
TICABRIL TABLET, FILM COATED 90MG	5044/21T	023301	TAD PHARMA GMBH	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by th C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by th C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s)
LOBIVON TABLET 5MG	2236/22T	022269	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
MEDOTIS TABLET, GASTRO-RESISTANT 20MG	8480/21T	021394	ZENTIVA K.S.	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
MEDOTIS TABLET, GASTRO-RESISTANT 10MG	8479/21T	021393	ZENTIVA K.S.	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
ROSU-ASA CAPSULE, HARD 5MG/100MG	2029/22T	023199	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSU-ASA CAPSULE, HARD 10MG/100MG	2030/22T	023200	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSU-ASA CAPSULE, HARD 20MG/100MG	2031/22T	023201	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	1374/22T	022925	OCTAPHARMA (IP) SPRL	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
LIPOPEN TABLET, FILM COATED 10MG/10MG	1265/22T	023319	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIPOPEN TABLET, FILM COATED 20MG/10MG	1266/22T	023320	ELPEN PHARMACEU	B.III.1.a.2 B.III.1.a.2 - QUALITY

			TICAL CO INC	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIPOPEN TABLET, FILM COATED 5MG/10MG	1264/22T	023318	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIPOPEN TABLET, FILM COATED 40MG/10MG	1267/22T	023321	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CLARISCAN SOLUTION FOR INJECTION 0.5MMOL/ML	1069/22T, 1070/22T	022730	GE HEALTHCARE AS	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	9330/21T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or

				starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
BORTEZOMIB/PHARMAZAC POWDER FOR SOLUTION FOR INJECTION 3.5MG/VIAL	1063/22T	022867	PHARMAZAC S.A.	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
FRAXIPARINE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 5700IU AXa/0.6ML	4137/21T, 4138/21T, 4139/21T, 4140/21T, 4141/21T, 4142/21T, 4143/21T, 4144/21T, 4145/21T	019117	MYLAN IRE HEALTHCARE LIMITED	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or star B.I.b.2.c B.I.b.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or star B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or star B.I.e.2 B.I.e.2 - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Introduction of a post app

				B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions o B.I.a.1.d B.I.a.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediat
FRAXIPARINE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 2850IU AXa/0.3ML	4128/21T, 4129/21T, 4130/21T, 4131/21T, 4132/21T, 4133/21T, 4134/21T, 4135/21T, 4136/21T	019116	MYLAN IRE HEALTHCARE LIMITED	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or star B.I.b.2.c B.I.b.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or star B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or star B.I.e.2 B.I.e.2 - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Design Space and post-approval change management protocols - Introduction of a post app B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions o B.I.a.1.d B.I.a.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediat
NEPHROTECT SOLUTION FOR INFUSION 10%	7014/21T, 7015/21T, 7016/21T	020261	FRESENIUS KABI HELLAS AE	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - Eur B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
FOLIFER TABLET, FILM COATED	538/22T	020218	BIAL-PORTELA & CA, SA	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Reduction in the testing frequency of an analysis, from routine testing to skip or periodic testing (microbial testing of finished product).
SMOFKABIVEN EXTRA NITROGEN ELECTROLYTE FREE EMULSION FOR INFUSION	9563/21T, 9564/21T, 9565/21T, 9566/21T, 9567/21T, 9568/21T, 9569/21T, 9570/21T	023283	FRESENIUS KABI HELLAS AE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.III.1.a.2 B.III.1.a.2 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
SMOFKABIVEN ELECTROLYTE FREE EMULSION FOR INFUSION	9571/21T, 9572/21T, 9573/21T, 9574/21T, 9575/21T, 9576/21T, 9577/21T, 9578/21T	020716	FRESENIUS KABI HELLAS AE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	9540/21T, 9541/21T, 9542/21T	023121	CSL BEHRING GMBH	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting

				material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele
BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	9537/21T, 9538/21T, 9539/21T	023120	CSL BEHRING GMBH	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the

				manufacturing process of the active substance - Addition of a new specification parameter to the specification w B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele
BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	9534/21T, 9535/21T, 9536/21T	022321	CSL BEHRING GMBH	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance -

				Addition of a new specification parameter to the specification w B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	9531/21T, 9532/21T, 9533/21T	020564	CSL BEHRING GMBH	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the

				specification w B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele
SERTRALINE ACCORD TABLET, FILM COATED 50MG	121/22T	022799	ACCORD HEALTHCARE S.L.U	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
SERTRALINE ACCORD TABLET, FILM COATED 100MG	120/22T	022800	ACCORD HEALTHCARE S.L.U	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
TICAGRELOR/MYLAN TABLET, FILM COATED 90MG	525/22T	023358	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
TICAGRELOR/MYLAN TABLET, FILM COATED 60MG	524/22T	023357	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	1911/22T	023447	MYLAN IRELAND LIMITED	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
SITAGLIPTIN/MYLAN TABLET, FILM COATED 100MG	1912/22T	023448	MYLAN IRELAND LIMITED	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a

				pack - Change within the range of the currently approved pack sizes
ALLUZIENCE SOLUTION FOR INJECTION 200 SPEYWOOD UNITS/ML	9222/21T, 9223/21T	023486	IPSEN PHARMA	B.II.b.4.f B.II.b.4.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
ATORVASTATIN UPJOHN TABLET, FILM COATED 80MG	8100/21T, 8101/21T	021892	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
SILDENAFIL/UPJOHN TABLET, FILM COATED 100MG	8092/21T, 8093/21T	021669	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products

SILDENAFIL/UPJOHN TABLET, FILM COATED 25MG	8088/21T, 8089/21T	021667	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
SILDENAFIL/UPJOHN TABLET, FILM COATED 50MG	8090/21T, 8091/21T	021668	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ATORVASTATIN UPJOHN TABLET, FILM COATED 40MG	8098/21T, 8099/21T	021891	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ELETRIPTAN/UPJOHN TABLET, FILM COATED 40MG	8096/21T, 8097/21T	023370	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ELETRIPTAN/UPJOHN TABLET, FILM COATED 20MG	8094/21T, 8095/21T	023369	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
NANOGAM SOLUTION FOR INFUSION 100MG/ML	1574/22T	023227	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a

				medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	2018/22T, 2019/22T, 2020/22T, 2021/22T, 2022/22T	022376	TEVA GMBH	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substanc B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finishe B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monogra
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	2013/22T, 2014/22T, 2015/22T, 2016/22T, 2017/22T	020187	TEVA GMBH	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substanc B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finishe B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monogra
TAZOCIN EF POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/VIAL	9738/21T, 9739/21T, 9740/21T, 9741/21T, 9742/21T	014384	PFIZER HELLAS AE	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.1.f B.I.b.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia
REVAMOX TABLET, FILM COATED 200MG	9787/21T	023581	GENEPHARM SA	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
VIMETSO TABLET, FILM COATED 50MG/850MG	1027/22T	023480	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VIMETSO TABLET, FILM COATED 50MG/1000MG	1028/22T	023481	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product -

				Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	1353/22T	020984	SANDOZ GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	1352/22T	020985	SANDOZ GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	1354/22T	020987	SANDOZ GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CITRAFLEET POWDER FOR ORAL SOLUTION	277/22T	022389	CASEN RECORDATI SL	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
VORICONAZOLE/ELPEN POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	1362/22T	023082	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR

				or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
RAMI-AMLO CAPSULE, HARD (10+5)MG	5212/21T	022125	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
RAMI-AMLO CAPSULE, HARD (10+10)MG	5211/21T	022127	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
RAMI-AMLO CAPSULE, HARD (5+10)MG	5213/21T	022126	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality,

				preclinical, clinical or pharmacovigilance data
RAMI-AMLO CAPSULE, HARD (2.5+5)MG	5215/21T	022123	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
RAMI-AMLO CAPSULE, HARD (5+5)MG	5214/21T	022124	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BORTEZOMIB/TEVA POWDER FOR SOLUTION FOR INJECTION 3.5MG/VIAL	1064/22T, 1065/22T, 1066/22T	023019	TEVA BV	B.I.d.1.a.1 B.I.d.1.a.1 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - Reduction B.I.b.1.b B.I.b.1.b - QUALITY CHANGES -

				ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss
APO-GO PFS SOLUTION FOR INFUSION 5MG/ML IN PREFILLED SYRINGE	326/22T	021474	ITF HELLAS A.E.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
APO-GO PFS SOLUTION FOR INFUSION 5MG/ML IN PREFILLED SYRINGE	326/22T	021474	ITF HELLAS A.E.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site,

				manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 22.5MG	8257/21T, 8258/21T	019686	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 45MG	8259/21T, 8260/21T	020460	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 7.5MG	8255/21T, 8256/21T	019687	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 45MG	817/22T, 818/22T, 819/22T, 820/22T, 821/22T, 822/22T, 823/22T, 824/22T, 825/22T, 826/22T	020460	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing

				B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 22.5MG	807/22T, 808/22T, 809/22T, 810/22T, 811/22T, 812/22T, 813/22T, 814/22T, 815/22T, 816/22T	019686	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.d.2.a B.II.d.2.a

				- QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 7.5MG	797/22T, 798/22T, 799/22T, 800/22T, 801/22T, 802/22T, 803/22T, 804/22T, 805/22T, 806/22T	019687	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
AMOXIL CAPSULE, HARD 500MG	1288/22T	019966	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
METHOTREXATE ACCORD SOLUTION FOR INJECTION 25MG/ML	642/22T	021631	ACCORD HEALTHCARE S.L.U	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
DONEPEZIL ACCORD TABLET, FILM COATED 10MG	62/22T	021472	ACCORD HEALTHCARE S.L.U	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DONEPEZIL ACCORD TABLET, FILM COATED 5MG	61/22T	021471	ACCORD HEALTHCARE S.L.U	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NETILMICIN/DEXAMETHASONE NEWLINE PHARMA EYE GEL (3MG/1MG)/ML	325/22T	023356	NEWLINE PHARMA, S.L.	C.I.8.a C.I.8.a - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
DEXAMETHASONE SODIUM PHOSPHATE NEWLINE PHARMA EYE DROPS, SOLUTION 1.5MG/ML	327/22T	023181	NEWLINE PHARMA, S.L.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
MEDOTIS TABLET, GASTRO-RESISTANT 20MG	1285/22T	021394	ZENTIVA K.S.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MEDOTIS TABLET, GASTRO-RESISTANT 10MG	1284/22T	021393	ZENTIVA K.S.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

WELLBUTRIN XR MODIFIED-RELEASE TABLET 300MG	7519/21T	020249	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
WELLBUTRIN XR MODIFIED-RELEASE TABLET 150MG	7518/21T	020248	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TICAGRELOR/MYLAN TABLET, FILM COATED 90MG	709/22T	023358	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
TICAGRELOR/MYLAN TABLET, FILM COATED 60MG	708/22T	023357	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
PLATOREL TABLET, FILM COATED 5MG	1967/22T	022553	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the

				manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
PLATOREL TABLET, FILM COATED 20MG	1969/22T	022555	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
PLATOREL TABLET, FILM COATED 40MG	1970/22T	022556	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
PLATOREL TABLET, FILM COATED 10MG	1968/22T	022554	ELPEN PHARMACEUTICAL CO INC	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	9318/21T	022376	TEVA GMBH	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or

				storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
NAVELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 50MG/5ML	351/21T	017884	PIERRE FABRE MEDICAMENT	C.I.6.a C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one
TAZOCIN EF POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/VIAL	8603/21T, 8604/21T	014384	PFIZER HELLAS AE	B.II.b.z B.II.b.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Other variation
LEVOXACIN TABLET, FILM COATED 500MG	9442/21T	020748	SAPIENS PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LEVOXACIN TABLET, FILM COATED 250MG	9441/21T	020747	SAPIENS PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TRIATEC PLUS TABLET 5MG/25MG	1039/22T	019071	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMLODIPINE/VALSARTAN/HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/12.5MG	1270/22T	023592	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/320MG/25MG	1272/22T	023594	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/25MG	1271/22T	023593	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/25MG	1269/22T	023591	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/12.5MG	1268/22T	023590	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NIPRUSS POWDER FOR SOLUTION FOR INFUSION 60MG/AMP	9472/21T	023202	ALTAMEDICS GMBH	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.f.z B.II.f.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Other variation
LEPONEX TABLET 25MG	5410/21T, 5411/21T, 5412/21T, 5413/21T, 5414/21T, 5415/21T, 5416/21T, 5417/21T, 5418/21T, 5419/21T, 5420/21T, 5421/21T, 5422/21T, 5423/21T	018390	MYLAN IRE HEALTHCARE LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the f B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finishe B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finishe B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release

				arrangements and B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo
LEPONEX TABLET 100MG	5424/21T, 5425/21T, 5426/21T, 5427/21T, 5428/21T, 5429/21T, 5430/21T, 5431/21T, 5432/21T, 5433/21T, 5434/21T, 5435/21T, 5436/21T, 5437/21T	018389	MYLAN IRE HEALTHCARE LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the f B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finishe B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the

				manufacturing process of the finishe B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	8043/21T	020187	TEVA GMBH	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal

				products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	8044/21T	022376	TEVA GMBH	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FULVESTRANT ROMPHARM SOLUTION FOR INJECTION IN PREFILLED SYRINGES 250MG/5ML	5378/21T, 5379/21T	023306	S.C. ROMPHARM COMPANY SRL	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier -

				Re-test period/storage period - B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
FULVESTRANT ROMPHARM SOLUTION FOR INJECTION IN PREFILLED SYRINGES 250MG/5ML	6732/21T	023306	S.C. ROMPHARM COMPANY SRL	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PLATOREL TABLET, FILM COATED 5MG	1364/22T	022553	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PLATOREL TABLET, FILM COATED 20MG	1366/22T	022555	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PLATOREL TABLET, FILM COATED 40MG	1367/22T	022556	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PLATOREL TABLET, FILM COATED 10MG	1365/22T	022554	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/320MG/25MG	920/22T	023594	GENEPHARM SA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations

				and conditions (e.g. agreed wording + QRD template)
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/25MG	919/22T	023593	GENEPHARM SA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/25MG	917/22T	023591	GENEPHARM SA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/12.5MG	921/22T	023590	GENEPHARM SA	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE	918/22T	023592	GENEPHARM SA	C.I.11.z C.I.11.z - SAFETY,

GENEPHARM TABLET, FILM COATED 10MG/160MG/12.5MG				EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
BLISSEL VAGINAL GEL 50MCG/G	4409/21T	023538	ITF HELLAS A.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ZYRTEC ORAL SOLUTION 0.1%	9474/21T	016365	UCB PHARMA SA	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
ZYRTEC TABLET, FILM COATED 10MG	9473/21T	013066	UCB PHARMA SA	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or

				batch release - Not including batch control/testing
TRIATEC TABLET 2.5MG	911/22T	012904	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TRIATEC TABLET 5MG	912/22T	012905	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VITIS VINIFERA/OPELLA TABLET, FILM COATED 360MG	1204/22T	023393	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
ZYRTEC ORAL SOLUTION 0.1%	695/22T	016365	UCB PHARMA SA	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
SILDENAFIL MYLAN TABLET, FILM COATED 50MG	741/22T	023104	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
SILDENAFIL MYLAN TABLET, FILM COATED 25MG	740/22T	023103	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products

SILDENAFIL MYLAN TABLET, FILM COATED 100MG	742/22T	023105	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
BUVERA PATCH, TRANSDERMAL 35MCG/h	9158/21T	022607	RAFARM S.A.	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
BUVERA PATCH, TRANSDERMAL 70MCG/h	9160/21T	022609	RAFARM S.A.	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a

				novel excipient (where specified in the technical dossier)
BUVERA PATCH, TRANSDERMAL 52.5MCG/h	9159/21T	022608	RAFARM S.A.	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
IVIVERZ TABLET, FILM COATED 600MG/300MG	9796/21T, 9797/21T, 9798/21T, 9799/21T	022685	ACCORD HEALTHCARE S.L.U	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or

				change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place
RAFUSTER CAPSULE, SOFT 0.5MG	5347/20T	022778	RAFARM S.A.	B.III.1 a) 2. Updated certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DICLODUO COMBI MODIFIED-RELEASE CAPSULE, HARD	702/22T	022360	PHARMASWISS CESKA REPUBLIKA SRO	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
SERETIDE EVOHALER PRESSURISED INHALATION, SUSPENSION 25MCG/50MCG	3967/21T, 3968/21T, 3969/21T, 3970/21T, 3971/21T, 6055/21T	019553	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.b.5.d B.II.b.5.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product B.IV.1.c B.IV.1.c - QUALITY

				CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is an integrated pa B.II.e.7.z B.II.e.7.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the d
LEVOFLOXACIN KABI SOLUTION FOR INFUSION 5MG/ML	7221/21T	20574	FRESENIUS KABI HELLAS AE	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
VILDAGLIPTIN PHARMATHEN TABLET 50MG	1254/22T	023063	PHARMATHEN S.A.	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in

				pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	9498/21T	023276	MYLAN IRE HEALTHCARE LIMITED	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	9497/21T	023275	MYLAN IRE HEALTHCARE LIMITED	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
CREON 10000 CAPSULE, HARD 150MG	9496/21T	018755	MYLAN IRE HEALTHCARE LIMITED	B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
ZOLOFT TABLET, FILM COATED 50MG	2236/21T	014677	UPJOHN HELLAS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ZOLOFT TABLET, FILM COATED 100MG	2237/21T	014678	UPJOHN HELLAS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OLARTAN-PLUS TABLET, FILM COATED 20MG/12.5MG	9308/21T	020333	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OLARTAN-PLUS TABLET, FILM COATED 40MG/12.5MG	9306/21T	021785	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OLARTAN-PLUS TABLET, FILM COATED 40MG/25MG	9307/21T	021786	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LOBIVON PLUS TABLET, FILM COATED 5MG/12.5MG	9304/21T	021788	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR

				or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ORIZAL PLUS TABLET, FILM COATED 40/10/12.5MG	9301/21T	021494	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	9300/21T	021493	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the

				assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	9303/21T	021496	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	9299/21T	021492	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent

				authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	9302/21T	021495	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LOBIVON PLUS TABLET, FILM COATED 5MG/25MG	9305/21T	021789	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of

				Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OLARTAN-PLUS TABLET, FILM COATED 20MG/25MG	9309/21T	020334	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/12.5MG	1130/22T	023592	GENEPHARM SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/320MG/25MG	1132/22T	023594	GENEPHARM SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/25MG	1131/22T	023593	GENEPHARM SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/25MG	1129/22T	023591	GENEPHARM SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/12.5MG	1128/22T	023590	GENEPHARM SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a

				marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
ROCURONIUM B.BRAUN SOLUTION FOR INJECTION OR INFUSION 10MG/ML	9204/21T	023414	B. BRAUN MELSUNGEN AG	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ARIMIDEX TABLET, FILM COATED 1MG	8721/21T, 8722/21T, 8723/21T	017100	LABORATOIRES JUVISE PHARMACEUTICALS	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the

				batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
VITIS VINIFERA/OPELLA TABLET, FILM COATED 360MG	836/22T	023393	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	292/22T	023566	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	290/22T	023563	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for

				the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	293/22T	023565	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	291/22T	023564	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PEMETREXED SEACROSS POWDER FOR	1585/22T	022843	SEACROSS PHARMA	A.4 A.4 - ADMINISTRATIVE

CONCENTRATE FOR SOLUTION FOR INFUSION 500MG/VIAL			(EUROPE) LIMITED	CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/VIAL	1586/22T	022842	SEACROSS PHARMA (EUROPE) LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
PALEXIA ORAL SOLUTION 20MG/ML	9493/21T, 9494/21T	022524	GRUNENTHAL GMBH	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

				the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes
ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 40MG	9779/21T, 9780/21T	020971	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 20MG	9777/21T, 9778/21T	020970	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
APO-GO PEN SOLUTION FOR INJECTION 10MG/ML	9795/21T	021473	ITF HELLAS A.E.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TAVANIC PARENTERAL SOLUTION FOR INFUSION 500MG/100ML	895/22T	019282	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TAVANIC TABLET, FILM COATED 500MG	894/22T	019283	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DEXALEAU ORAL SOLUTION 10MG/5ML	6930/21T	022121	VELKA HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
DEXALEAU ORAL SOLUTION 20MG/5ML	6931/21T	022122	VELKA HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LIPOPEN TABLET, FILM COATED 10MG/10MG	9385/21T	023319	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the

				outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LIPOPEN TABLET, FILM COATED 20MG/10MG	9386/21T	023320	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LIPOPEN TABLET, FILM COATED 5MG/10MG	9384/21T	023318	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LIPOPEN TABLET, FILM COATED 40MG/10MG	9387/21T	023321	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FINGOLIMOD PHARMASCIENCE CAPSULE, HARD 0.5MG	1040/22T	023482	PHARMASCIENCE INTERNATIONAL LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including

				replacement or addition)
IMIPENEM/CILASTATIN APTAPHARMA POWDER FOR SOLUTION FOR INFUSION 500MG/500MG	2840/21T, 2841/21T, 2842/21T	023377	APTA MEDICA INTERNACIONAL D.O.O.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ELOMEN SOLUTION FOR INFUSION (10MG/3MG)/ML	7677/21T, 7678/21T	023289	MEDOCHEMIE LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of

				pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
BLISSEL VAGINAL GEL 50MCG/G	4041/21T	023538	ITF HELLAS A.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
RAPIBLOC POWDER FOR SOLUTION FOR INFUSION 300MG/VIAL	66/22T, 67/22T	022744	AMOMED PHARMA GMBH.	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
TEKCIS RADIONUCLIDE GENERATOR 2-50 GBq	5105/21T	021787	CIS BIO INTERNATIONAL	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File

AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	9659/21T	020968	IPSEN PHARMA	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
BUSCOFEM CAPSULE, SOFT 400MG	6381/21T	022424	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	8031/21T, 8032/21T	023308	OCTAPHARMA (IP) SPRL	B.II.b.3.c B.II.b.3.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - The product is a biological/immunological medicinal product and the

				change requires an assessment of comparability B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
TAPTIQOM EYE DROPS, SOLUTION (15MCG/5MG)/ML	710/22T	023572	VIANEX S.A	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	5786/21T, 5787/21T	023231	BAUSCH + LOMB IRELAND LIMITED	B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
NUROFEN LIQUID CAPSULE, SOFT 200MG	9719/21T	020918	RECKITT BENCKISER HELLAS HEALTHCAR E SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site,

				manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
BUSCOFEM CAPSULE, SOFT 400MG	8183/21T	022424	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
FINGOLIMOD PHARMASCIENCE CAPSULE, HARD 0.5MG	624/22T	023482	PHARMASCIENCE INTERNATIONAL LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
TIOTROPIUM DEMO INHALATION POWDER, HARD CAPSULE 18MCG	737/22T, 738/22T	023456	DEMO S.A.	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification

				parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 10MG	6115/21T	023251	PHARMASCIENCE INTERNATIONAL LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 15MG	6116/21T	023252	PHARMASCIENCE INTERNATIONAL LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the

				active substance supported by an ASMF
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 5MG	6114/21T	023250	PHARMASCIENCE INTERNATIONAL LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 25MG	6117/21T	023253	PHARMASCIENCE INTERNATIONAL LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM	898/22T	023592	GENEPHARM SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY,

COATED 10MG/160MG/12.5MG				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/320MG/25MG	900/22T	023594	GENEPHARM SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 10MG/160MG/25MG	899/22T	023593	GENEPHARM SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/25MG	897/22T	023591	GENEPHARM SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
AMLODIPINE/VALSARTAN /HYDROCHLOROTHIAZIDE GENEPHARM TABLET, FILM COATED 5MG/160MG/12.5MG	896/22T	023590	GENEPHARM SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
EZETIMIBE/MYLAN TABLET 10MG	9331/21T	023155	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
RIDOCA CAPSULE, HARD 100MG	8278/21T	022132	AENORASIS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
RIDOCA CAPSULE, HARD 250MG	8281/21T	022135	AENORASIS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
RIDOCA CAPSULE, HARD 140MG	8279/21T	022133	AENORASIS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer

				(replacement or addition)
RIDOCA CAPSULE, HARD 20MG	8277/21T	022131	AENORASIS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
RIDOCA CAPSULE, HARD 180MG	8280/21T	022134	AENORASIS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
RIDOCA CAPSULE, HARD 5MG	8276/21T	022130	AENORASIS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	8973/21T, 8974/21T, 8975/21T	020968	IPSEN PHARMA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DUCILTIA GASTRO-RESISTANT CAPSULE, HARD 30MG	6497/21T	022499	PHARMATHEN S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of

				wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
DUCILTIA GASTRO-RESISTANT CAPSULE, HARD 60MG	6498/21T	022500	PHARMATHEN S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ACTILYSE CATHFLO POWDER FOR SOLUTION FOR INJECTION/INFUSION 2MG	1287/22T	023354	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	4172/21T	023032	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product -

				Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 50MG/12.5MG	4171/21T	023031	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY,

				EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
LOSARTAN AUROBINDO TABLET, FILM COATED 50MG	5611/21T	023012	AUROBINDO PHARMA (MALTA) LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8282/21T, 8283/21T, 8284/21T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s) B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change

				in the shelf-life or storage conditions of the finished product - Other variation B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
ROSUVASTATIN/MYLAN TABLET, FILM COATED 10MG	464/22T, 465/22T, 466/22T	022929	MYLAN IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
ROSUVASTATIN/MYLAN TABLET, FILM COATED 40MG	470/22T, 471/22T, 472/22T	022931	MYLAN IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
ROSUVASTATIN/MYLAN TABLET, FILM COATED 5MG	461/22T, 462/22T, 463/22T	022928	MYLAN IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - Eur
ROSUVASTATIN/MYLAN TABLET, FILM COATED 20MG	467/22T, 468/22T, 469/22T	022930	MYLAN IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
PRAGIOLA CAPSULE, HARD 75MG	386/22T, 387/22T	022689	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PRAGIOLA CAPSULE, HARD 150MG	388/22T, 389/22T	022690	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PRAGIOLA CAPSULE, HARD 300MG	390/22T, 391/22T	022691	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PRAGIOLA CAPSULE, HARD 25MG	384/22T, 385/22T	022688	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
AZYTER EYE DROPS, SOLUTION 15MG/G	6634/21T	021320	LABORATOIRES THEA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DEXAFREE EYE DROPS, SOLUTION 1MG/ML	8335/21T, 8336/21T	021770	LABORATOIRES THEA	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 200IU/ML(1000IU/5ML)	536/22T	023296	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 100IU/ML(500IU/5ML)	537/22T	023295	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250/500 (50 IU/ml)	534/22T	020061	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000 (100 IU/ml)	535/22T	020062	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZYVOXID TABLET, FILM COATED 600MG	4394/21T	023036	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or

				pharmacovigilance data
ZYVOXID SOLUTION FOR INFUSION 2MG/ML	4395/21T	023035	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/40MG	563/22T, 564/22T	023128	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/10MG	559/22T, 560/22T	023126	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/20MG	561/22T, 562/22T	023127	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.2.b A.2.b - ADMINISTRATIVE

				CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
NIPRUSS POWDER FOR SOLUTION FOR INFUSION 60MG/AMP	931/22T	023202	ALTAMEDICS GMBH	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
MAYMETSI TABLET, FILM COATED 50MG/1000MG	9831/21T	023375	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MAYMETSI TABLET, FILM COATED 50MG/850MG	9832/21T	023374	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TORVACARD TABLET, FILM COATED 20MG	11001/20T	020931	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TORVACARD TABLET, FILM COATED 10MG	11002/20T	020930	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal

				products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TORVACARD TABLET, FILM COATED 40MG	11000/20T	020932	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TORVACARD TABLET, FILM COATED 80MG	10999/20T	020933	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to

				be submitted by the MAH
MUCOCOLD TABLET, FILM COATED 200MG/30MG	276/22T	021691	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	204/22T, 205/22T, 206/22T, 207/22T, 208/22T, 209/22T, 210/22T, 211/22T	020200	BAXALTA INNOVATIONS GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The

				activities A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	212/22T, 213/22T, 214/22T, 215/22T, 216/22T, 217/22T, 218/22T, 219/22T	020201	BAXALTA INNOVATIONS GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	196/22T, 197/22T, 198/22T, 199/22T, 200/22T, 201/22T, 202/22T, 203/22T	020199	BAXALTA INNOVATIONS GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF

				holder; or a supplier of the active substan A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
XYZAL ORAL SOLUTION 0.5MG/ML	759/22T	020127	UCB PHARMA SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
XYZAL TABLET, FILM COATED 5MG	758/22T	020044	UCB PHARMA SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PALIPERIDON TAD TABLET, PROLONGED-RELEASE 6MG	444/22T	023014	TAD PHARMA GMBH	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
PALIPERIDON TAD TABLET, PROLONGED-RELEASE 9MG	445/22T	023015	TAD PHARMA GMBH	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a

				starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
PALIPERIDON TAD TABLET, PROLONGED-RELEASE 3MG	443/22T	023013	TAD PHARMA GMBH	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
VALSARTAN KRKA TABLET, FILM COATED 80MG	9756/21T	020833	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TAZOCIN EF POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/VIAL	341/22T, 342/22T	014384	PFIZER HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.a.2.z B.I.a.2.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Other changes
SEROPRAM TABLET, FILM COATED 20MG	9329/21T	016117	LUNDBECK HELLAS A.E.,CYPRUS	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk

				management plan - Other RMP changes (e.g. agreed wording + template change)
ANDROXIL CUTANEOUS SOLUTION 2%	6950/21T, 6951/21T, 6952/21T, 6953/21T, 6954/21T, 6955/21T, 6956/21T	022100	LABORATOIRES BAILLEUL S.A	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Reduction in the testing frequency of an analysis, from routine testing to skip B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsol B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ANDROXIL CUTANEOUS SOLUTION 5%	6943/21T, 6944/21T, 6945/21T, 6946/21T, 6947/21T, 6948/21T, 6949/21T	022101	LABORATOIRES BAILLEUL S.A	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Reduction in the testing frequency of an analysis, from routine testing to skip B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsol B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ROPESAR TABLET, PROLONGED-RELEASE 2MG	850/22T	022221	P T HADJIGEORGIOU CO LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ROPESAR TABLET, PROLONGED-RELEASE 4MG	852/22T	022223	P T HADJIGEORGIOU CO LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ROPESAR TABLET, PROLONGED-RELEASE 8MG	853/22T	022224	P T HADJIGEORGIOU CO LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient -

				European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ROPESAR TABLET, PROLONGED-RELEASE 3MG	851/22T	022222	P T HADJIGEORGIOU CO LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 16MG/12.5MG	9449/21T	021247	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

				Updated certificate from an already approved manufacturer
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/25MG	9451/21T	021249	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/12.5MG	9450/21T	021248	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 8MG/12.5MG	9448/21T	021246	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ACTILYSE POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1MG/ML	969/22T	023353	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ACTILYSE CATHFLO POWDER FOR SOLUTION FOR INJECTION/INFUSION 2MG	968/22T	023354	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TORVACARD NEO TABLET, FILM COATED 20MG	9200/21T	022248	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for

				the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TORVACARD NEO TABLET, FILM COATED 80MG	9198/21T	022250	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TORVACARD NEO TABLET, FILM COATED 40MG	9199/21T	022249	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

TORVACARD NEO TABLET, FILM COATED 10MG	9201/21T	022247	ZENTIVA K.S.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BORTEZOMIB STADA SOLUTION FOR INJECTION 2.5MG/ML	9438/21T	023431	STADA ARZNEIMITTEL AG	B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that affects the product information
HYDROCORTISONE RENATA TABLET 20MG	92/22T, 93/22T, 94/22T, 95/22T	023444	RENATA PHARMACEUTICALS (IRELAND) LIMITED	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes B.II.b.3.a B.II.b.3.a - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
HYDROCORTISONE RENATA TABLET 10MG	88/22T, 89/22T, 90/22T, 91/22T	023443	RENATA PHARMACEUTICALS (IRELAND) LIMITED	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
CARAMLO TABLET 5MG/8MG	9446/21T	022063	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CARAMLO TABLET 10MG/16MG	9445/21T	022064	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (4G/0.5G)/VIAL	9221/21T	020530	MYLAN IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment

PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (2G/0.25G)/VIAL	9220/21T	020529	MYLAN IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
DIAZEPAM ACCORD TABLET 5MG	581/22T, 582/22T, 583/22T, 584/22T, 585/22T, 586/22T, 587/22T, 588/22T, 589/22T, 590/22T, 591/22T, 592/22T, 593/22T, 594/22T, 595/22T, 596/22T, 597/22T	023466	ACCORD HEALTHCARE S.L.U	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - R B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - R B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - R B.II.a.3.b.1 B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an ac B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.c.1.b B.II.c.1.b - QUALITY CHANGES - FINISHED

				PRODUCT - Control of exci B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of fini B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of fini B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closu
DIAZEPAM ACCORD TABLET 10MG	598/22T, 599/22T, 600/22T, 601/22T, 602/22T, 603/22T, 604/22T, 605/22T, 606/22T, 607/22T, 608/22T, 609/22T, 610/22T, 611/22T, 612/22T, 613/22T, 614/22T	023467	ACCORD HEALTHCARE S.L.U	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - R B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - R B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - R B.II.a.3.b.1 B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of

				manufacturing sites for an ac B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.c.1.b B.II.c.1.b - QUALITY CHANGES - FINISHED PRODUCT - Control of exci B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - C B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of fini B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of fini B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closu
NETILMICIN/DEXAMETHASONE NEWLINE PHARMA EYE GEL (3MG/1MG)/ML	9781/21T	023356	NEWLINE PHARMA, S.L.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DYSPORT POWDER FOR SOLUTION FOR INJECTION 500U	3936/21T, 3937/21T	019337	IPSEN M.E.P.E.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
MOXIFALON T TABLET, FILM COATED 400MG	1632/21T	022568	DEMO S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
AMIODARONE AUROBINDO TABLET 200MG	9383/21T	022398	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
GRANULOKINE SINGLEJECT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 30 MU (0,6 MG/ML)	3697/21T, 3698/21T	019765	AMGEN EUROPE B.V.	B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol

GRANULOKINE SOLUTION FOR INJECTION 0.3MG/ML VIAL	3695/21T, 3696/21T	019764	AMGEN EUROPE B.V.	B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol
GRANULOKINE SINGLEJECT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 48 MU (0,96 MG/ML)	3699/21T, 3700/21T	019766	AMGEN EUROPE B.V.	B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/

				immunological/ immunochemical test method or a method using a biological reagent for a biological active substance B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol
TEKCIS RADIONUCLIDE GENERATOR 2-50 GBq	626/22T, 627/22T	021787	CIS BIO INTERNATIONAL	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
OLIMEL N9 EMULSION FOR INFUSION	9712/21T, 9713/21T, 9714/21T	022013	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL N12E EMULSION FOR INFUSION	9706/21T, 9707/21T, 9708/21T	023257	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL N7 EMULSION FOR INFUSION	9709/21T, 9710/21T, 9711/21T	022012	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL N9E EMULSION FOR INFUSION	9703/21T, 9704/21T, 9705/21T	022011	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL PERI N4E EMULSION FOR INFUSION	9697/21T, 9698/21T, 9699/21T	022008	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OLIMEL N7E EMULSION FOR INFUSION	9700/21T, 9701/21T, 9702/21T	022010	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BUFAR EASYHALER POWDER FOR INHALATION 80MCG/4.5MCG/INHALATION	9100/21T, 9101/21T	022432	ORION CORPORATION (ORION PHARMA)	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) B.III.1.a.3 B.III.1.a.3 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
BUFAR EASYHALER POWDER FOR INHALATION 160/4.5MCG/INHALATION	9096/21T, 9097/21T	022088	ORION CORPORATION (ORION PHARMA)	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
BUFAR EASYHALER POWDER FOR INHALATION 320/9MCG/INHALATION	9098/21T, 9099/21T	022089	ORION CORPORATION (ORION PHARMA)	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ROSU-ASA CAPSULE, HARD 5MG/100MG	8166/21T	023199	IASIS PHARMACEUTICALS HELLAS SA	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES -

				FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
ROSU-ASA CAPSULE, HARD 10MG/100MG	8167/21T	023200	IASIS PHARMACEUTICALS HELLAS SA	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
ROSU-ASA CAPSULE, HARD 20MG/100MG	8168/21T	023201	IASIS PHARMACEUTICALS HELLAS SA	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
SCABALL TABLET 3MG	9813/21T, 9814/21T	023537	EPSILON HEALTH (NESTORAS VLACHOS P.C.)	B.I.d.1.b.1 B.I.d.1.b.1 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering

				the retest period is part of the approved dossier - Storage conditions - Change to more restrictive storage conditions of the active substance B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
IRBESARTAN ACCORD TABLET, FILM COATED 150MG	8988/21T, 8989/21T	021645	ACCORD HEALTHCARE S.L.U	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place

VALGANCICLOVIR AUROBINDO TABLET, FILM COATED 450MG	3469/21T	022358	AUROBINDO PHARMA (MALTA) LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
CONCERTA TABLET, PROLONGED-RELEASE 54MG	8980/21T	020336	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CONCERTA TABLET, PROLONGED-RELEASE 18MG	8978/21T	020339	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CONCERTA TABLET, PROLONGED-RELEASE 36MG	8979/21T	020340	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
HEXARHINAL PLUS NASAL SPRAY, SOLUTION (1MG/50MG)/ML	7565/21T, 7566/21T, 7567/21T, 7568/21T, 7569/21T, 7570/21T, 7571/21T, 7572/21T, 7573/21T, 7574/21T, 7575/21T, 7576/21T, 7577/21T, 7578/21T, 7579/21T, 7580/21T, 7581/21T, 7582/21T, 7583/21T, 7584/21T, 7585/21T, 7586/21T, 7587/21T, 7588/21T, 7589/21T, 7590/21T	023376	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - M B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - M B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - M B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - M A.7 A.7 - ADMINISTRATIVE CHANGES -

				Deletion of manufacturing s B.II.b.4.b B.II.b.4.b - QUALITY CHANGES - FINISHED PRODUCT - M B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - M B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - M B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - M B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - M B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - C B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - C B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - C B.II.d.2.e B.II.d.2.e - QUALITY CHANGES - FINISHED PRODUCT - C B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - C
AFEKSIN SOLUBLE TABLET 20MG	1689/21T, 1690/21T	023442	TEVA BV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
RINGER LACTATE/BAXTER(VIAFLO) SOLUTION FOR INFUSION	328/22T	020066	BAXTER (HELLAS) EPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DEXAFREE EYE DROPS, SOLUTION 1MG/ML	5093/21T	021770	LABORATORIES THEA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SMOFLIPID EMULSION FOR INFUSION 20%	9763/21T, 9764/21T, 9765/21T, 9766/21T	020184	FRESENIUS KABI HELLAS AE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
NOSATEL TABLET, FILM COATED 25MG	8875/21T, 8876/21T, 8877/21T, 8878/21T, 8879/21T, 8880/21T, 8881/21T	020154	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.1.z B.II.c.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Other changes B.II.c.2.z B.II.c.2.z - QUALITY CHANGES - FINISHED

				PRODUCT - Control of excipients - Change in test procedure for an excipient - Other variation
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	7426/21T	022376	TEVA GMBH	B.I.d.1.z B.I.d.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Other variation
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	7425/21T	020187	TEVA GMBH	B.I.d.1.z B.I.d.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Other variation
NUROFEN FOR CHILDREN 4% STRAWBERRY ORAL SUSPENSION 4%	9717/21T	021713	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NUROFEN FOR CHILDREN 4% STRAWBERRY ORAL SUSPENSION 4%	9717/21T	021713	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active

				substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NUROFEN FOR CHILDREN 4% ORANGE ORAL SUSPENSION 4%	9718/21T	021712	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	8026/21T	023308	OCTAPHARMA (IP) SPRL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100/12.5MG	9048/21T	020921	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LENIGRON EYE DROPS, SOLUTION (0.3MG/5MG)/ML	512/22T	023007	PHARMATHEN S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PROCTO-GLYVENOL SUPPOSITORY	5017/21T, 5018/21T, 5019/21T, 5020/21T, 5021/21T, 5022/21T, 5023/21T	018327	RECORDATI HELLAS PHARMACEUTICALS SA	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b

				- QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finis B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase o B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used
NUROFEN FOR CHILDREN ORANGE CHEWABLE CAPSULE, SOFT 100MG	9521/21T	022496	RECKITT BENCKISER HELLAS HEALTHCAR E SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

MEROPENEM VENUS POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	153/21T, 154/21T	021662	VENUS PHARMA GMBH	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
MEROPENEM VENUS POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/VIAL	151/21T, 152/21T	021663	VENUS PHARMA GMBH	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
VITAROS CREAM 3MG/G	8084/21T	022375	RECORDATI IRELAND LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer

VITAROS CREAM 2MG/G	8083/21T	022374	RECORDATI IRELAND LTD	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
MENTIFAR TABLET, FILM COATED 20MG	81/22T	022205	RAFARM S.A.	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings
MENTIFAR TABLET, FILM COATED 10MG	80/22T	022204	RAFARM S.A.	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings
LOGNIF CAPSULE, HARD 0.5MG	9283/21T	023340	TEVA GMBH	C.I.11.z C.I.11.z - SAFETY,

				EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
MELPHALAN TILLOMED POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 50MG/VIAL	8039/21T, 8040/21T, 8041/21T, 8042/21T, 8898/21T	022629	TILLOMED PHARMA GMBH.	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes B.II.f.1.e B.II.f.1.e - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change to an approved stability protocol B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally app B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product,

				including an intermediate used in the manufacture of the finishe B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w
TOPAMAX TABLET, FILM COATED 200MG	8570/21T, 8571/21T, 8572/21T	018278	JANSSEN-CILAG INTERNATIONAL NV	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release -

				Including batch control/testing
TOPAMAX TABLET, FILM COATED 25MG	8564/21T, 8565/21T, 8566/21T	018277	JANSSEN-CILAG INTERNATIONAL NV	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
TOPAMAX TABLET, FILM COATED 50MG	8573/21T, 8574/21T, 8575/21T	018276	JANSSEN-CILAG INTERNATIONAL NV	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product -

				Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
TOPAMAX TABLET, FILM COATED 100MG	8567/21T, 8568/21T, 8569/21T	018275	JANSSEN-CILAG INTERNATIONAL NV	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging

				site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
TOLTERODINE ACCORD TABLET, FILM COATED 2MG	1161/22T, 1162/22T	020875	ACCORD HEALTHCARE S.L.U	B.II.b.2 c) 1. Not including batch control/testing
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 16MG/12.5MG	9746/21T	021247	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/25MG	9745/21T	021249	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/12.5MG	9744/21T	021248	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment,

				e.g. translations are not yet agreed upon
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 8MG/12.5MG	9743/21T	021246	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
VAXIGRIPTETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	9671/21T	022512	SANOFI PASTEUR.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	8761/21T	022522	ACCORD HEALTHCARE S.L.U	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
METHOTREXATE ACCORD SOLUTION FOR INJECTION 25MG/ML	9370/21T	021631	ACCORD HEALTHCARE S.L.U	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
APREDONAV TABLET, FILM COATED 7.5MG	119/22T	022918	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product -

				Implementation of change(s) for which no new additional data is required to be submitted by the MAH
APREDONAV TABLET, FILM COATED 5MG	118/22T	022919	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROPESAR TABLET, PROLONGED-RELEASE 2MG	9120/21T	022221	P T HADJIGEORGIOU CO LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ROPESAR TABLET, PROLONGED-RELEASE 4MG	9122/21T	022223	P T HADJIGEORGIOU CO LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ROPESAR TABLET, PROLONGED-RELEASE 8MG	9123/21T	022224	P T HADJIGEORGIOU CO LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ROPESAR TABLET, PROLONGED-RELEASE 3MG	9121/21T	022222	P T HADJIGEORGIOU CO LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF

CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	87/22T	019161	SANOFI-AVENTIS GROUPE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	85/22T	019160	SANOFI-AVENTIS GROUPE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	84/22T	019159	SANOFI-AVENTIS GROUPE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	86/22T	019744	SANOFI-AVENTIS GROUPE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
APO-GO PEN SOLUTION FOR INJECTION 10MG/ML	8263/21T	021473	ITF HELLAS A.E.	B.II.e.5.a.2 B.II.e.5.a.2 -

				QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	9552/21T	023231	BAUSCH + LOMB IRELAND LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TIOTROPIUM DEMO INHALATION POWDER, HARD CAPSULE 18MCG	641/22T	023456	DEMO S.A.	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
PANTOFLUX TABLET, GASTRO-RESISTANT 20MG	7947/21T	022045	ACTAVIS GROUP PTC EHF	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference

				product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PANTOFLUX TABLET, GASTRO-RESISTANT 40MG	7948/21T	022046	ACTAVIS GROUP PTC EHF	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VOLULYTE SOLUTION FOR INFUSION 6%	9483/21T	20656	FRESENIUS KABI DEUTSCHLAND GMBH, GERMANY	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product,

				where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
DUOMAX TABLET, FILM COATED 500MG/150MG	11003/20T, 11004/20T, 11005/20T, 11006/20T	023101	MEDOCHE MIE LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of

				manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	9434/21T	023032	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 50MG/12.5MG	9433/21T	023031	KRKA D.D. NOVO MESTO	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure

				concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
QUELORAN TABLET, PROLONGED-RELEASE 300MG	4713/21T	023410	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
QUELORAN TABLET, PROLONGED-RELEASE 150MG	4711/21T	023408	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended

				to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
QUELORAN TABLET, PROLONGED-RELEASE 400MG	4714/21T	023411	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
QUELORAN TABLET, PROLONGED-RELEASE 200MG	4712/21T	023409	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
QUELORAN TABLET, PROLONGED-RELEASE 50MG	4710/21T	023407	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TOLTERODINE ACCORD TABLET, FILM COATED 2MG	2683/21T	020875	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for

				the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
IRBESARTAN ACCORD TABLET, FILM COATED 150MG	7610/21T	021645	ACCORD HEALTHCARE S.L.U	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
CELEBREX CAPSULE, HARD 100MG	6702/21T	023174	UPJOHN HELLAS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
CELEBREX CAPSULE, HARD 200MG	6703/21T	023173	UPJOHN HELLAS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
XEOMIN POWDER FOR SOLUTION FOR INJECTION 200 UNITS	4373/21T	022628	MERZ PHARMACEU	C.I.4 C.I.4 - SAFETY, EFFICACY,

			TICALS GMBH	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	4371/21T	022001	MERZ PHARMACEUTICALS GMBH	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	4372/21T	022002	MERZ PHARMACEUTICALS GMBH	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ULTIMAX ALTER TABLET, FILM COATED 400MG	3714/21T	023392	MEDOCHEMIE LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension

				of the shelf life of the finished product - As packaged for sale (supported by real time data)
ULTIMAX ALTER TABLET, FILM COATED 200MG	3713/21T	023391	MEDOCHEMIE LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
FUSIDIC ACID/BETAMETHASONE VALERATE PHARMASCIENCE INTERNATIONAL CREAM (20MG/1MG)/G	304/22T, 305/22T, 306/22T	022726	PHARMASCIENCE INTERNATIONAL LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release

CINACALCET/RAFARM TABLET, FILM COATED 90MG	889/22T, 890/22T, 891/22T, 892/22T, 893/22T	023396	RAFARM S.A.	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
CINACALCET/RAFARM TABLET, FILM COATED 60MG	884/22T, 885/22T, 886/22T, 887/22T, 888/22T	023395	RAFARM S.A.	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
CINACALCET/RAFARM TABLET, FILM COATED 30MG	879/22T, 880/22T, 881/22T, 882/22T, 883/22T	023394	RAFARM S.A.	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)

ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	5386/21T	023144	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	5384/21T	023142	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	5383/21T	023141	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	5385/21T	023143	ACCORD HEALTHCARE S.L.U	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MILDRONATE CAPSULE, HARD 500MG	9418/21T, 9419/21T	023526	AS GRINDEKS	A.2.b A.2.b - ADMINISTRATIVE

				CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
SOLPADEINE COLD & FLU CAPSULE, HARD 500MG/100MG/6.1MG	529/22T	023546	OMEGA PHARMA HELLAS S.A	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100/12.5MG	4824/21T, 6173/21T	020921	KRKA D.D. NOVO MESTO	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
LOSARTAN KRKA TABLET, FILM COATED 50MG	4184/21T	20678	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference

				product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
LOSARTAN KRKA TABLET, FILM COATED 25MG	4183/21T	20677	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by

				the MAH (e.g. comparability)
LOSARTAN KRKA TABLET, FILM COATED 100MG	4185/21T	20679	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
LOSARTAN KRKA TABLET, FILM COATED 12.5MG	4182/21T	20676	KRKA D.D. NOVO MESTO	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
ONCOTICE POWDER FOR SOLUTION FOR INFUSION	4551/21T	019017	MSD AFVEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 500MG/VIAL	4264/21T	022843	SEACROSS PHARMA (EUROPE) LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/VIAL	4263/21T	022842	SEACROSS PHARMA (EUROPE) LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF

PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	6984/21T	019080	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/25MG	9785/21T	023159	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/12.5MG	9783/21T	023157	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure

				concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OLMEDIPIN PLUS TABLET, FILM COATED 20MG/5MG/12.5MG	9782/21T	023156	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/12.5MG	9784/21T	023158	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the

				outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/25MG	9786/21T	023160	MYLAN IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SALOFALK SUPPOSITORY 1G	8754/21T, 8755/21T	020945	DR. FALK PHARMA GMBH	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
PLATOREL TABLET, FILM COATED 5MG	9628/21T	022553	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PLATOREL TABLET, FILM COATED 20MG	9630/21T	022555	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PLATOREL TABLET, FILM COATED 40MG	9631/21T	022556	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PLATOREL TABLET, FILM COATED 10MG	9629/21T	022554	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FERINJECT SOLUTION FOR INJECTION OR INFUSION 50MG IRON/ML	6748/21T	020795	VIFOR FRANCE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
FINGOLIMOD PHARMATHEN CAPSULE, HARD 0.5MG	6700/21T, 6701/21T	023228	PHARMATHEN S.A.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including

				contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
FINGOLIMOD PHARMATHEN CAPSULE, HARD 0.5MG	9127/21T	023228	PHARMATHEN S.A.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	9093/21T	022603	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GLUCOSE 5%/BAXTER (VIAFLO) SOLUTION FOR INFUSION 5% W/V	9095/21T	019767	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SODIUM CHLORIDE/BAXTER(VIAFLO) SOLUTION FOR INFUSION 0.9% W/V	9094/21T	020065	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CONVERIDE TABLET, FILM COATED 300MG/25MG	4877/21T	022219	MEDOCHEMIE LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
CONVERIDE TABLET, FILM COATED 300MG/12.5MG	4876/21T	022218	MEDOCHEMIE LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
CONVERIDE TABLET, FILM COATED 150MG/12.5MG	4875/21T	022217	MEDOCHE MIE LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
XYZAL ORAL SOLUTION 0.5MG/ML	9455/21T	020127	UCB PHARMA SA	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
XYZAL TABLET, FILM COATED 5MG	9454/21T	020044	UCB PHARMA SA	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the

				finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
TEVETEN PLUS TABLET, FILM COATED 600MG/12.5MG	9336/21T	020235	VIATRIS HEALTHCARE GMBH	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TADALAFIL SANDOZ TABLET, FILM COATED 20MG	497/22T	022668	SANDOZ GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur.

				Monograph - Updated certificate from an already approved manufacturer
TADALAFIL SANDOZ TABLET, FILM COATED 5MG	498/22T	022667	SANDOZ GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BREXIN TABLET 20MG	7039/21T, 7040/21T, 7041/21T, 7042/21T, 7043/21T	014762	CHIESI HELLAS A.E.B.E.	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally app B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used

				in the manufacture of the finishe B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w
TOPAMAX SPRINKLES CAPSULE, HARD 25MG	9091/21T	019576	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TOPAMAX TABLET, FILM COATED 200MG	9088/21T	018278	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TOPAMAX TABLET, FILM COATED 25MG	9092/21T	018277	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TOPAMAX TABLET, FILM COATED 50MG	9086/21T	018276	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TOPAMAX TABLET, FILM COATED 100MG	9087/21T	018275	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
TOPAMAX SPRINKLES CAPSULE, HARD 50MG	9090/21T	019557	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TOPAMAX SPRINKLES CAPSULE, HARD 15MG	9089/21T	019558	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SKUDEXA TABLET, FILM COATED 75MG/25MG	5466/21T	022464	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
SKUDEXA GRANULES FOR ORAL SOLUTION 75MG/25MG	5465/21T	023030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of

				wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
NOSATEL TABLET, FILM COATED 25MG	5469/21T	020154	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
NOSATEL SOLUTION FOR INJECTION OR INFUSION 50MG/2ML	5468/21T	020155	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

NOSATEL GRANULES FOR ORAL SOLUTION 25MG	5467/21T	022622	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ARLEVERT TABLET	8708/21T, 8709/21T	021476	HENNIG ARZNEIMITTEL GMBH & CO KG	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test

				procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
TAZOCIN EF POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/VIAL	9371/21T, 9372/21T, 9373/21T, 9374/21T	014384	PFIZER HELLAS AE	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
ALERTAN TABLET, FILM COATED 10MG	9453/21T	020752	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet

				intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ALERTAN TABLET, FILM COATED 5MG	9452/21T	020751	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
VITAROS CREAM 3MG/G	9491/21T	022375	RECORDATI IRELAND LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 100U	4218/21T	023324	MERZ PHARMACEUTICALS GMBH	B.II.a.3.b.3 B.II.a.3.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a

				biological/immunological product
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 50U	4217/21T	023325	MERZ PHARMACEUTICALS GMBH	B.II.a.3.b.3 B.II.a.3.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product
XEOMIN POWDER FOR SOLUTION FOR INJECTION 200 UNITS	4219/21T	022628	MERZ PHARMACEUTICALS GMBH	B.II.a.3.b.3 B.II.a.3.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product
XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	4221/21T	022001	MERZ PHARMACEUTICALS GMBH	B.II.a.3.b.3 B.II.a.3.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product
XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	4220/21T	022002	MERZ PHARMACEUTICALS GMBH	B.II.a.3.b.3 B.II.a.3.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a

				biological/immunological product
LOBIVON PLUS TABLET, FILM COATED 5MG/12.5MG	6838/21T, 6839/21T, 6840/21T, 6841/21T, 6842/21T, 6843/21T, 6844/21T	021788	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised
LOBIVON PLUS TABLET, FILM COATED 5MG/25MG	6831/21T, 6832/21T, 6833/21T, 6834/21T, 6835/21T, 6836/21T, 6837/21T	021789	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished

				product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised
NUROFEN EXPRESS CAPSULE, SOFT 400MG	9105/21T	021486	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
STREPFEN DIRECT HONEY & LEMON OROMUCOSAL SPRAY, SOLUTION 8.75MG	9103/21T	023399	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
STREPFEN DIRECT CHERRY & MINT OROMUCOSAL SPRAY 8.75MG	9104/21T	022717	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ANDROXIL CUTANEOUS SOLUTION 5%	9229/21T	022101	LABORATOIRES BAILLEUL S.A	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)

ANDROXIL CUTANEOUS SOLUTION 2%	9230/21T	022100	LABORATOIRES BAILLEUL S.A	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
ANDROXIL CUTANEOUS SOLUTION 5%	8608/21T	022101	LABORATOIRES BAILLEUL S.A	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits
ROSU-ASA CAPSULE, HARD 5MG/100MG	8169/21T, 8170/21T	023199	IASIS PHARMACEUTICALS HELLAS SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details)

				and/or changes in the Pharmacovigilance System Master File (PSMF) location
ROSU-ASA CAPSULE, HARD 10MG/100MG	8171/21T, 8172/21T	023200	IASIS PHARMACEUTICALS HELLAS SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
ROSU-ASA CAPSULE, HARD 20MG/100MG	8173/21T, 8174/21T	023201	IASIS PHARMACEUTICALS HELLAS SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* -

				Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
EZETIMIBE/MYLAN TABLET 10MG	7477/21T, 7478/21T	023155	MYLAN IRELAND LIMITED	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
ULTIMAX ALTER TABLET, FILM COATED 400MG	7921/21T	023392	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
ULTIMAX ALTER TABLET, FILM COATED 200MG	7920/21T	023391	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TIENAM POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	7988/21T	021719	MERCK SHARP & DOHME BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
WELLBUTRIN XR MODIFIED-RELEASE TABLET 300MG	5897/21T	020249	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method

WELLBUTRIN XR MODIFIED-RELEASE TABLET 150MG	5896/21T	020248	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	3410/21T	020187	TEVA GMBH	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	3411/21T	022376	TEVA GMBH	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
RISPERDAL TABLET, FILM COATED 3MG	8752/21T	014398	JANSSEN-CILAG INTERNATIONAL NV	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES -

				FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
RISPERDAL TABLET, FILM COATED 4MG	8753/21T	014399	JANSSEN-CILAG INTERNATIONAL NV	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
RISPERDAL TABLET, FILM COATED 2MG	8751/21T	014397	JANSSEN-CILAG INTERNATIONAL NV	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
RISPERDAL TABLET, FILM COATED 1MG	8750/21T	014396	JANSSEN-CILAG INTERNATIONAL NV	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
DROLL EAR DROPS SOLUTION 1MG	9447/21T	023352	GALENICA SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LIPOCAT TABLET, FILM COATED 10MG/40MG	8148/21T	023451	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIPOCAT TABLET, FILM COATED 10MG/20MG	8147/21T	023450	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur.

				Monograph - Updated certificate from an already approved manufacturer
LIPOCAT TABLET, FILM COATED 10MG/80MG	8149/21T	023452	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIPOCAT TABLET, FILM COATED 10MG/10MG	8146/21T	023449	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

CANDESARTAN KRKA TABLET 16MG	8485/21T	021503	KRKA D.D. NOVO MESTO	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
DEFERASIROX MSN TABLET, FILM COATED 180MG	8266/21T, 8267/21T	023423	MSN LABS EUROPE LIMITED	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
DEFERASIROX MSN TABLET, FILM COATED 90MG	8264/21T, 8265/21T	023422	MSN LABS EUROPE LIMITED	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
DEFERASIROX MSN TABLET, FILM COATED 360MG	8268/21T, 8269/21T	023424	MSN LABS EUROPE LIMITED	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the

				finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
HEXARHINAL NASAL SPRAY, SOLUTION 1MG/ML	7611/21T, 7612/21T, 7613/21T, 7614/21T, 7615/21T, 7616/21T, 7617/21T, 7618/21T, 7619/21T, 7620/21T, 7621/21T, 7622/21T, 7623/21T, 7624/21T, 7625/21T, 7626/21T, 7627/21T	020981	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-pr B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the m A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to impor B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to i B.II.b.1.a B.II.b.1.a

				- QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 225IU	9235/21T	021853	IBSA FARMACEUTICI ITALIA SRL	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	9233/21T	021778	IBSA FARMACEUTICI ITALIA SRL	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	9238/21T	020234	IBSA FARMACEUTICI ITALIA SRL	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	9234/21T	021777	IBSA FARMACEUTICI ITALIA SRL	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 300IU	9236/21T	021854	IBSA FARMACEUTICI ITALIA SRL	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	9237/21T	020233	IBSA FARMACEUTICI ITALIA SRL	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the

				active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
FLEXBUMIN SOLUTION FOR INFUSION 200G/L	9650/21T	020477	BAXALTA INNOVATIONS GMBH	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
FLEXBUMIN SOLUTION FOR INFUSION 250G/L	9649/21T	020478	BAXALTA INNOVATIONS GMBH	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
MICROLAX RECTAL SOLUTION (0.45G/0.0645G/4.465G)/DOSE	6271/21T, 6272/21T, 6273/21T, 6274/21T, 6275/21T, 6276/21T	022712	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finis B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used
BUDENOFALK UNO GASTRO-RESISTANT GRANULES 9MG	8733/21T	022433	DR. FALK PHARMA GMBH	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
TERIPARATIDE/TEVA B.V. SOLUTION FOR INJECTION IN A PRE-FILLED PEN 20MCG/80MCL	9162/21T	023299	TEVA BV	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
FLECTOR TISSUGEL MEDICATED PLASTER 1%	9672/21T, 9673/21T	020149	IBSA FARMACEUTICI ITALIA SRL	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	8920/21T, 8921/21T	020571	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	8924/21T, 8925/21T	020573	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	8922/21T, 8923/21T	020572	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	8918/21T, 8919/21T	020570	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ATORVASTATIN GENERICS TABLET, FILM COATED 10MG	8351/21T	021893	GENERICS PHARMA HELLAS LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ATORVASTATIN GENERICS TABLET, FILM COATED 20MG	8353/21T	021894	GENERICS PHARMA HELLAS LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for

				Nationally Authorised Products
ATORVASTATIN GENERICS TABLET, FILM COATED 40MG	8352/21T	021895	GENERICS PHARMA HELLAS LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
GENEMENT TABLET, FILM COATED 5MG	9494/20T	023123	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GENEMENT TABLET, FILM COATED 20MG	9493/20T	023124	GENEPHARM SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COLCHICINE RENATA TABLET 500MCG	9124/21T, 9125/21T, 9126/21T	023433	RENATA PHARMACEUTICALS (IRELAND) LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible

				include batch release
REVAMOX TABLET, FILM COATED 200MG	9674/21T, 9675/21T	023581	GENEPHARM SA	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	8986/21T, 8987/21T	023032	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 50MG/12.5MG	8984/21T, 8985/21T	023031	KRKA D.D. NOVO MESTO	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FEMI TABLET 0.250MG/0.035MG	9648/21T	023355	ITF HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DUROGESIC PATCH, TRANSDERMAL 100MCG/H	8871/21T	017987	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DUROGESIC PATCH, TRANSDERMAL 50MCG/H	8870/21T	017986	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DUROGESIC PATCH, TRANSDERMAL 25MCG/H	8869/21T	017985	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/40MG	9321/21T	023128	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/10MG	9319/21T	023126	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/20MG	9320/21T	023127	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FUROSEMIDE BRISTOL TABLET 40MG	9075/21T	022480	BRILLPHARMA (IRELAND) LIMITED	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	7679/21T	022522	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	332/21T, 333/21T	023238	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
HALDOL ORAL SOLUTION 2MG/ML	9228/21T	006153	JANSSEN-CILAG INTERNATIONAL NV	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to

				an approved test procedure
IMMUNATE 500 IU FVIII/375 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/5ML	9543/21T	020085	BAXALTA INNOVATIONS GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
IMMUNATE 250 IU FVIII/190 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250IU/5ML	9545/21T	020084	BAXALTA INNOVATIONS GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
IMMUNATE 1000 IU FVIII/750 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/10ML	9544/21T	020086	BAXALTA INNOVATIONS GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
BILENI NASAL SPRAY, SUSPENSION	2893/21T	021884	MEDA PHARMACEUTICALS S.A.	C.I.6.a C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one
DONEPEZIL KRKA TABLET, FILM COATED 5MG	8106/21T	021435	KRKA D.D. NOVO MESTO	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
DONEPEZIL KRKA TABLET, FILM COATED 10MG	8107/21T	021436	KRKA D.D. NOVO MESTO	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/25MG	8289/21T	023159	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/12.5MG	8287/21T	023157	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the

				(invented) name of the medicinal product - for Nationally Authorised Products
OLMEDIPIN PLUS TABLET, FILM COATED 20MG/5MG/12.5MG	8286/21T	023156	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/12.5MG	8288/21T	023158	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/25MG	8290/21T	023160	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
TEKCIS RADIONUCLIDE GENERATOR 2-50 GBq	8983/21T	021787	CIS BIO INTERNATIONAL	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
LAMBRINEX TABLET, FILM COATED 40MG	9528/21T	021002	PHARMATHEN S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient

				(when mentioned in the dossier)*
LAMBRINEX TABLET, FILM COATED 80MG	9529/21T	021003	PHARMATHEN S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LAMBRINEX TABLET, FILM COATED 20MG	9527/21T	021001	PHARMATHEN S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LAMBRINEX TABLET, FILM COATED 10MG	9526/21T	021000	PHARMATHEN S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FUROSEMIDE BRISTOL TABLET 40MG	9217/21T, 9218/21T, 9219/21T	022480	BRILLPHARMA (IRELAND) LIMITED	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
BLISSEL VAGINAL GEL 50MCG/G	9524/21T	023538	ITF HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ROSUVADOR TABLET, FILM COATED 40MG	6830/21T	022627	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ROSUVADOR TABLET, FILM COATED 20MG	6829/21T	022626	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ROSUVADOR TABLET, FILM COATED 5MG	6827/21T	022624	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure

				concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ROSUVADOR TABLET, FILM COATED 10MG	6828/21T	022625	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 20MG	8488/21T	021780	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product

				Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 40MG	8487/21T	021781	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VIANIB CAPSULE, HARD 400MG	8895/21T	022455	VIANEX S.A	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
VIANIB CAPSULE, HARD 100MG	8894/21T	022454	VIANEX S.A	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
MEDSAMIC SOLUTION FOR INJECTION 100MG/ML	8707/21T	021959	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NUROFEN EXPRESS CAPSULE, SOFT 400MG	5507/21T	021486	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ANAGRELIDE AOP CAPSULE, HARD 0.5MG	7272/21T, 7273/21T	023145	AOP ORPHAN PHARMACEUTICALS GMBH	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the

				finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
OLARTAN TABLET, FILM COATED 40MG	4794/21T	019690	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
OLARTAN-PLUS TABLET, FILM COATED 20MG/12.5MG	4792/21T	020333	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
OLARTAN-PLUS TABLET, FILM COATED 40MG/12.5MG	4790/21T	021785	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement

				(excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
OLARTAN-PLUS TABLET, FILM COATED 40MG/25MG	4791/21T	021786	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL TABLET, FILM COATED 40MG/10MG	4789/21T	020614	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL TABLET, FILM COATED 40MG/5MG	4788/21T	020613	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition

				or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ORIZAL TABLET, FILM COATED 20MG/5MG	4787/21T	020612	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
OLARTAN-PLUS TABLET, FILM COATED 20MG/25MG	4793/21T	020334	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
OLARTAN TABLET, FILM COATED 20MG	4795/21T	019689	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished

				product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
OLARTAN TABLET, FILM COATED 10MG	4796/21T	019688	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
NANOGAM SOLUTION FOR INFUSION 100MG/ML	8632/21T	023227	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	B.I.d.1.z B.I.d.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Other variation
MODIODAL TABLET 100MG	7520/21T, 7521/21T, 7522/21T, 7523/21T, 7524/21T, 7525/21T, 7526/21T, 7527/21T, 7528/21T, 7529/21T	018944	TEVA BV	B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in th B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of

				excipients - Change in sourc B.II.b.4.b B.II.b.4.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, b B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition o B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition o B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition o B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in th

BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	8865/21T, 8866/21T	023121	CSL BEHRING GMBH	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BORTEZOMIB/TEVA POWDER FOR SOLUTION FOR INJECTION 3.5MG/VIAL	8673/21T	023019	TEVA BV	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
OCTAGAM SOLUTION FOR INFUSION 10%	8600/21T	020717	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
METRONIDAZOLE B.BRAUN SOLUTION FOR INFUSION 5MG/ML	10494/20T	020463	B. BRAUN MELSUNGEN AG	B.II.d.3 B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product
ISSOFERROL TABLET, FILM COATED 180MG	9132/21T, 9133/21T	023484	ELPEN PHARMACEUTICAL CO INC	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
ISSOFERROL TABLET, FILM COATED 360MG	9134/21T, 9135/21T	023485	ELPEN PHARMACEUTICAL CO INC	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the

				restricted part of an Active Substance Master File B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
ISSOFERROL TABLET, FILM COATED 90MG	9130/21T, 9131/21T	023483	ELPEN PHARMACEUTICAL CO INC	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
DELTIUS CAPSULE, HARD 25000IU	5788/21T	023059	ITF HELLAS A.E.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for

				the finished product - Other changes to a test procedure (including replacement or addition)
DELTIUS CAPSULE, HARD 50000IU	5789/21T	023060	ITF HELLAS A.E.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
TEGLUTIK ORAL SUSPENSION 5MG/ML	9076/21T	023512	ITF HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	8601/21T	022925	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	9479/21T	022511	SANOFI PASTEUR.	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national

				pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	8355/21T	020200	BAXALTA INNOVATIONS GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	8356/21T	020201	BAXALTA INNOVATIONS GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	8354/21T	020199	BAXALTA INNOVATIONS GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ACTILYSE CATHFLO POWDER FOR SOLUTION FOR INJECTION/INFUSION 2MG	3917/21T, 3918/21T, 3919/21T, 3920/21T, 3921/21T	023354	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Other variation
SRIVASSO INHALATION POWDER, HARD CAPSULE 18MCG	1137/21T	022341	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
SPIRIVA INHALATION POWDER, HARD CAPSULE 18MCG	1138/21T	021138	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
VERRIA TABLET, FILM COATED 50MG	8381/21T	022536	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

VERRIA TABLET, FILM COATED 200MG	8382/21T	022537	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DULSEVIA GASTRO-RESISTANT CAPSULE, HARD 30MG	6889/21T	022814	KRKA D.D. NOVO MESTO	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
DULSEVIA GASTRO-RESISTANT CAPSULE, HARD 60MG	6890/21T	022815	KRKA D.D. NOVO MESTO	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
DALMEVIN TABLET 50MG	8249/21T	022644	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/12.5MG	164/22T	022572	TAD PHARMA GMBH	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by

				the competent authority
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/12.5MG	166/22T	022574	TAD PHARMA GMBH	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/25MG	167/22T	022575	TAD PHARMA GMBH	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/25MG	165/22T	022573	TAD PHARMA GMBH	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
METHYLPHENIDATE HCL SANDOZ TABLET,	1426/21T	021505	SANDOZ GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY,

PROLONGED-RELEASE 18MG				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 36MG	1427/21T	021506	SANDOZ GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 54MG	1428/21T	021507	SANDOZ GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
OCTAGAM SOLUTION FOR INFUSION 10%	8357/21T, 8358/21T	020717	OCTAPHARMA (IP) SPRL	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer,

				batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	6525/21T	022376	TEVA GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	6524/21T	020187	TEVA GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the

				active substance or a starting material/intermediate
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	8347/21T, 8348/21T	022925	OCTAPHARMA (IP) SPRL	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
RINGER LACTATE/BAXTER(VIAFLO) SOLUTION FOR INFUSION	9154/21T	020066	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TICOVAC SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.5ML/DOSE	6432/21T, 6433/21T, 6434/21T, 6435/21T, 6436/21T, 6437/21T	023266	PFIZER HELLAS AE	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active

				substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
TICOVAC JUNIOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.25ML/DOSE	6426/21T, 6427/21T, 6428/21T, 6429/21T, 6430/21T, 6431/21T	023267	PFIZER HELLAS AE	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes

				B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
IRINOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	6624/21T	022453	ACCORD HEALTHCARE S.L.U	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
FOLIFER TABLET, FILM COATED	9453/20T	020218	BIAL-PORTELA & CA, SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
DEXAMETHASONE/RAFARM [PF] EYE DROPS, SOLUTION 1MG/ML	8475/21T	023006	RAFARM S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CITRAFLEET POWDER FOR ORAL SOLUTION	5351/21T	022389	CASEN RECORDATI SL	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
FEMARA TABLET, FILM COATED 2.5MG	11062/20T, 11063/20T, 11064/20T, 11065/20T, 11066/20T, 11067/20T, 11068/20T, 11069/20T, 11070/20T, 11071/20T, 11072/20T, 11073/20T, 11074/20T	018468	NOVARTIS IRELAND LIMITED	B.I.a.1.z B.I.a.1.z - Addition of an alternative site for manufacture and/or storage of the AS (if it's not part of the same pharmaceutical group). If the site is already registered (and is in SIAMED) B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing

				process of the active substance - Minor change in the manufacturing process of the active substanc B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate /
HALDOL ORAL SOLUTION 2MG/ML	8592/21T	006153	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
HALDOL INJECTION 5MG/ML	8593/21T	006152	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
HALDOL DECANOAS INJECTION 100MG/1ML	8597/21T	009669	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
HALDOL DECANOAS INJECTION 50MG/1ML	8596/21T	009667	JANSSEN-CILAG INTERNATIONAL NV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MECOLZINE SUPPOSITORY 1000MG	364/21T	023298	FAES FARMA SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal

				products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MECOLZINE SUPPOSITORY 500MG	365/21T	023297	FAES FARMA SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AFEKSIN SOLUBLE TABLET 20MG	9161/21T	023442	TEVA BV	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MOLAXOLE POWDER FOR ORAL SOLUTION	3915/21T	20659	MEDA PHARMACEUTICALS S.A.	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
PANTOFLUX TABLET, GASTRO-RESISTANT 20MG	9187/21T	022045	ACTAVIS GROUP PTC EHF	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PANTOFLUX TABLET, GASTRO-RESISTANT 40MG	9188/21T	022046	ACTAVIS GROUP PTC EHF	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EPLERENONE ACCORD TABLET, FILM COATED 50MG	3775/21T	022369	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
EPLERENONE ACCORD TABLET, FILM COATED 25MG	3776/21T	022368	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following

				assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TRAVOPROST/RAFARM EYE DROPS, SOLUTION 40MCG/ML	6321/21T	022220	RAFARM S.A.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SADERON TABLET, FILM COATED 2.5MG	4646/22T, 4647/22T	022803	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ENIDAP CAPSULE, HARD 50MG	3344/22T	020829	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of

				wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ENIDAP CAPSULE, HARD 100MG	3345/22T	020830	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
SOLPADEINE SOLUBLE TABLET	3503/22T	019779	OMEGA PHARMA HELLAS S.A	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by

				the competent authority that do not require any further assessment
ENIDAP CAPSULE, HARD 50MG	3339/22T	020829	IASIS PHARMACEUTICALS HELLAS SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ENIDAP CAPSULE, HARD 100MG	3338/22T	020830	IASIS PHARMACEUTICALS HELLAS SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
SOLPADEINE TABLET	3505/22T	019780	OMEGA PHARMA HELLAS S.A	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
APONIL TABLET 100MG	3490/22T	017417	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LANSO GASTRO-RESISTANT CAPSULE, HARD 30MG	4180/22T, 4181/22T	020737	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
HEXALEN OROMUCOSAL SOLUTION 5MG/5ML	4079/21T	006685	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
LAMOSYNT TABLET 25MG	2258/22T	021487	CODAL-SYNTO LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
HEXALEN OROMUCOSAL SPRAY 0.2%	3996/21T	006780	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
REZAVIR TABLET, FILM COATED 300MG	1879/22T	022548	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
REZAVIR TABLET, FILM COATED 800MG	1882/22T	022551	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
REZAVIR TABLET, FILM COATED 75MG	1877/22T	022546	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
REZAVIR TABLET, FILM COATED 400MG	1880/22T	022549	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the

				same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
REZAVIR TABLET, FILM COATED 150MG	1878/22T	022547	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
REZAVIR TABLET, FILM COATED 600MG	1881/22T	022550	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

LYBEREN TABLET, FILM COATED 750MG	3950/22T	021963	ELPEN PHARMACEUTICAL CO INC	B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)
LYBEREN TABLET, FILM COATED 500MG	3949/22T	021962	ELPEN PHARMACEUTICAL CO INC	B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)
LYBEREN TABLET, FILM COATED 250MG	3948/22T	021961	ELPEN PHARMACEUTICAL CO INC	B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)
LYBEREN TABLET, FILM COATED 1000MG	3951/22T	021964	ELPEN PHARMACEUTICAL CO INC	B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)

MEDOTRAMOL TABLET, FILM COATED 37.5MG/325MG	3477/22T	022288	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
QUETRA ORAL SOLUTION 100MG/ML	3985/22T	021968	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FELEXIN CAPSULE, HARD 250MG	4405/22T	019696	REMEDICA LTD	C.z C.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Other variation

				C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
FELEXIN CAPSULE, HARD 500MG	4406/22T	019701	REMEDICA LTD	C.z C.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Other variation C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
GABANTIN CAPSULE, HARD 400MG	3514/22T	020736	IASIS PHARMACEUTICALS HELLAS SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GABANTIN CAPSULE, HARD 300MG	3513/22T	020735	IASIS PHARMACEUTICALS HELLAS SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GABANTIN CAPSULE, HARD 400MG	3781/22T	020736	IASIS PHARMACEU	C.I.3.z C.I.3.z - SAFETY,

			TICALS HELLAS SA	EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
GABANTIN CAPSULE, HARD 300MG	3780/22T	020735	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent

				authority that require additional minor assessment, e.g. translations are not yet agreed upon
TEZOL TABLET, GASTRO-RESISTANT 100MG	3736/22T, 3737/22T	023437	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas
TEZOL TABLET, GASTRO-RESISTANT 100MG	3701/22T	023437	DELORBIS PHARMACEUTICALS LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
TEZOL TABLET, GASTRO-RESISTANT 100MG	3596/22T	023437	DELORBIS PHARMACEUTICALS LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in

				the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
VIDEL TABLET 50MG	3073/22T	023400	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MOVATEC TABLET 15MG	3614/21T, 3615/21T, 3616/21T, 3617/21T, 3618/21T, 3619/21T, 3620/21T, 3621/21T, 3622/21T, 3623/21T	019616	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished

				product - Change in the specification parameters and/or limits of the finished produc B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.d.1.i B.II.d.1.i - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage co B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion o
MOVATEC TABLET 7.5MG	3604/21T, 3605/21T, 3606/21T, 3607/21T, 3608/21T, 3609/21T, 3610/21T, 3611/21T, 3612/21T, 3613/21T	019617	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT -

				Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.d.1.i B.II.d.1.i - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage co B.II.c.1.c B.II.c.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Deletion o
REMEDOL SUPPOSITORY 125MG	3801/22T	019737	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended

				to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REMEDOL SUPPOSITORY 500MG	3797/22T	014627	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REMEDOL SUPPOSITORY 250MG	3800/22T	014626	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REMEDOL FC TABLET, FILM COATED 500MG	3798/22T	018666	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PARACETAMOL-REMEDICA TABLET 500MG	3803/22T	014427	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR

				or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REMEDOL ORAL SUSPENSION 120MG/5ML	3802/22T	008526	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REMEDOL 6+ ORAL SUSPENSION 250MG/5ML	3799/22T	014425	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the

				assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REMEDOL TABLET 500MG	3796/22T	019665	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
GRAFALON CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	3157/22T, 3158/22T, 3159/22T	017186	NEOVII BIOTECH GMBH	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an

				active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer
VIVIDRIN EYE DROPS 2%	3900/21T	011977	DR.GERHARD MANN CHEM.-PHARM. FABRIK GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Submission of results of assessments carried out on target patient groups in order to comply with Article 59(3) of Directive 2001/83/EC and any resulting change to the Package Leaflet
BUTOLIR NEBULISER SUSPENSION 0.5MG/2ML	3938/21T, 3939/21T, 7466/21T, 7467/21T, 7468/21T	023051	NORIDEM ENTERPRISES LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes

BUTOLIR NEBULISER SUSPENSION 1MG/2ML	3940/21T, 3941/21T, 7469/21T, 7470/21T, 7471/21T	023052	NORIDEM ENTERPRISES LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
LAMOTRIX TABLET 25MG	1210/22T	018540	MEDOCHEMIE LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
AMLODIPINE/IASIS CAPSULE, HARD 10MG	2262/22T	021606	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance

				For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
AMLODIPINE/IASIS CAPSULE, HARD 5MG	2261/22T	021605	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
BRONCOTERIL INHALATION POWDER, HARD CAPSULE 12MCG	3479/22T	020576	IASIS PHARMACEUTICALS HELLAS SA	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
DEXAMYTREX EYE DROPS	6670/21T	011980	DR.GERHARD MANN CHEM.-PHARM.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation

			FABRIK GMBH	
DEXAMYTREX EYE OINTMENT	6669/21T	011976	DR.GERHARD MANN CHEM.-PHARM. FABRIK GMBH	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LOFOTO EYE DROPS, SUSPENSION	3507/22T	017820	RAFARM S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CARBIMAZOLE TABLET, FILM COATED 5MG	7265/21T	009336	REMEDICA LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
AVERNOL TABLET 25MG	913/22T	020151	MEDOCHEMIE LTD	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms
REVAMOX TABLET, FILM COATED 200MG	7464/21T	023581	GENEPHARM SA	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT -

				Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
FUCICORT CREAM	3910/22T, 3911/22T	008675	LEO PHARMA A/S	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
FUCIDIN CREAM 2%	3912/22T, 3913/22T	007588	LEO PHARMA A/S	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OTRIVIN NASAL DROPS 0.05%	6295/20T	017437	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ	A.1 Change in the name and/or address of the marketing authorisation holder

			ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	
OTRIVIN NASAL DROPS 0.1%	6294/20T	017436	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
FENISTIL GEL 0.1%	6302/20T	009660	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
SINECOD SYRUP 0.15%	6288/20T	017781	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
PANADOL TABLET, FILM COATED 500MG	6352/20T	019901	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.1 Change in the name and/or address of the marketing authorisation holder
PANADOL SOLUBLE EFFERVESCENT TABLET 500MG	6289/20T	019900	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙ	A.1 Change in the name and/or address of the

			ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	marketing authorisation holder
PANADOL EXTRA ADVANCE TABLET, FILM COATED 500MG/65MG	6290/20T	022031	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
PANADOL ACTIFAST TABLET 500MG	6293/20T	019435	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.1 Change in the name and/or address of the marketing authorisation holder
OTRIVIN PRESERVATIVE FREE NASAL SPRAY, SOLUTION 0.1% W/V	6298/20T	022849	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
LAMISIL ONCE CUTANEOUS SOLUTION 1%	6301/20T	021831	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
VOLTAREN EMUGEL GEL 1%	6286/20T	018989	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ	A.1 Change in the name and/or address of the

			ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	marketing authorisation holder
PANADOL ADVANCE TABLET, FILM COATED 500MG	6292/20T	021168	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
OTRIVIN NASAL GEL 0.1%	6296/20T	017438	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
OTRIVIN NASAL SPRAY 0.1%	6297/20T	017439	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
LAMISIL CUTANEOUS SPRAY 1%	6299/20T	017495	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder

COMTREX COLD TABLET, FILM COATED 500MG/30MG/2MG	6304/20T	016475	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
VIBROCIL-S NASAL DROPS	6287/20T	012889	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
LAMISIL CREAM 1%	6300/20T	018386	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
FENISTIL ORAL DROPS SOLUTION 1MG/ML(=20 DROPS)	6303/20T	009662	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 Change in the name and/or address of the marketing authorisation holder
PANADOL BABY & INFANT ORAL SUSPENSION 120MG/5ML	6291/20T	019770	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ	A.1 Change in the name and/or address of the marketing authorisation holder

			ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	
DIVIDOL TABLET, COATED 10MG	3704/22T	019675	REMEDICA LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
COMTREX COLD TABLET, FILM COATED 500MG/30MG/2MG	3868/22T	016475	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
KIVIZIDIALE EYE DROPS, SOLUTION (40MCG/5MG)/ML	6918/21T	023220	BAUSCH + LOMB IRELAND LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	938/20T	023566	AUROBINDO PHARMA (MALTA) LIMITED	B.II.f.1 b) 1. As packaged for sale (supported by real time data)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	941/20T	023563	AUROBINDO PHARMA (MALTA) LIMITED	B.II.f.1 b) 1. As packaged for sale (supported by real time data)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	939/20T	023565	AUROBINDO PHARMA (MALTA) LIMITED	B.II.f.1 b) 1. As packaged for sale (supported by real time data)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	940/20T	023564	AUROBINDO PHARMA (MALTA) LIMITED	B.II.f.1 b) 1. As packaged for sale (supported by real time data)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	10075/20T	023566	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional

				data is required to be submitted by the MAH
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	10072/20T	023563	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	10074/20T	023565	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	10073/20T	023564	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ZOMIG TABLET, FILM COATED 2.5MG	1058/22T	017688	C G PAPALOISOU LTD	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product
ZOMIG TABLET, FILM COATED 2.5MG	3243/22T, 3244/22T	017688	C G PAPALOISOU LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MUCOSOLVAN PROLONGED RELEASE CAPSULES 75MG	3393/22T	019781	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

KIVALA TABLET, FILM COATED	3118/22T	022346	REMEDICA LTD	B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
BUVERA PATCH, TRANSDERMAL 35MCG/h	5701/21T, 5702/21T	022607	RAFARM S.A.	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
BUVERA PATCH, TRANSDERMAL 70MCG/h	5705/21T, 5706/21T	022609	RAFARM S.A.	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product

				- Minor changes to an approved test procedure
BUVERA PATCH, TRANSDERMAL 52.5MCG/h	5703/21T, 5704/21T	022608	RAFARM S.A.	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PARCOTEN TABLET 500MG/10MG	3947/22T	016100	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

BINOSTO EFFERVESCENT TABLET 70MG	5516/21T	023029	GALENICA SA	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
PARCOTEN COLD & FLU TABLET, FILM COATED 500MG/30MG/15MG/60MG	3942/22T	023235	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ACEPROTIN TABLET 50MG	3893/22T	020003	CODAL SYNTO LTD	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph.

				Eur. or with a national pharmacopoeia of a Member State - Active substance
ACEPROTIN TABLET 25MG	3892/22T	020002	CODAL SYNTO LTD	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
REXANIB TABLET, FILM COATED 400MG	3153/22T	023438	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
REXANIB TABLET, FILM COATED 200MG	3154/22T	023207	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet

				intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
NIZORAL SHAMPOO 20MG/G	3702/22T	012220	STADA ARZNEIMITTEL AG	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
MABRON CAPSULE, HARD 50MG	8712/21T	012119	MEDOCHEMIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	3707/22T	012082	PFIZER HELLAS AE	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
LAMISIL TABLET 250MG	3160/22T, 3161/22T	018385	NOVARTIS IRELAND LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure

				system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
ACTILYSE POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1MG/ML	3807/21T, 3808/21T, 3809/21T, 3810/21T, 3811/21T, 3812/21T, 3813/21T, 3814/21T	023353	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	B.II.e.1.a.3 B.II.e.1.a.3 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile m B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deleti B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (suc B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or

				devices (when mentioned in the dossier) - Replacement or addition B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation
ZINACEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 750MG	9359/21T	019521	GLAXOSMITHKLINE (IRELAND) LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ZINACEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 1.5G	9361/21T	019520	GLAXOSMITHKLINE (IRELAND) LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ALGOFEN DUOFAST TABLET	3188/22T	019989	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
PARACETAMOL ACCORD TABLET 500MG	6408/21T, 6409/21T, 6410/21T, 6411/21T	022579	ACCORD HEALTHCARE S.L.U	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the

				manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc
LOPERIUM CAPSULE, HARD 2MG	3481/22T	008682	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LOPERIUM TABLET 2MG	3480/22T	019736	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ALGOFEN SUPPOSITORY 1000MG	3193/22T	011767	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal

				products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ALGOFEN SUPPOSITORY 125MG	3190/22T	011766	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ALGOFEN SUPPOSITORY 500MG	3192/22T	011769	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the

				outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ALGOFEN SUPPOSITORY 250MG	3191/22T	011768	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
BROT TABLET, FILM COATED 850MG	3469/22T	018506	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BROT TABLET, FILM COATED 500MG	3468/22T	009817	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FORTUM POWDER FOR SOLUTION FOR INJECTION 1G/VIAL	8624/20T	019519	GLAXOSMI THKLINE (IRELAND) LIMITED	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
FORTUM POWDER FOR SOLUTION FOR INJECTION 1G/VIAL	9355/21T	019519	GLAXOSMI THKLINE (IRELAND) LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AFEKSIN SOLUBLE TABLET 20MG	3867/22T	023442	ACTAVIS GROUP PTC EHF	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
COALIMAX TABLET 40/12.5MG	3500/22T	021923	DELORBIS PHARMACEU TICALS LTD	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including

				replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings
GRABILEN CAPSULE, HARD 75MG	3517/22T	023038	CODAL-SYNTO LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
GRABILEN CAPSULE, HARD 150MG	3518/22T	023039	CODAL-SYNTO LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
GRABILEN CAPSULE, HARD 300MG	3519/22T	023040	CODAL-SYNTO LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
BINOSTO EFFERVESCENT TABLET 70MG	5514/21T, 5515/21T	023029	GALENICA SA	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
BINOSTO EFFERVESCENT TABLET 70MG	5511/21T	023029	GALENICA SA	B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and immediate packaging materials
FAMVIR TABLET, FILM COATED 125MG	6383/21T	016371	PHOENIX LABS UNLIMITED COMPANY	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product -

				Secondary packaging site
FAMVIR TABLET, FILM COATED 250MG	6384/21T	016080	PHOENIX LABS UNLIMITED COMPANY	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
LEVOXA TABLET, FILM COATED 500MG	229/21T, 230/21T, 231/21T, 232/21T, 233/21T, 234/21T	021993	ACTAVIS GROUP PTC EHF	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharm B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Maste B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer

				(including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substan B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
NITROFURANTOIN/IASIS ORAL SUSPENSION 25MG/5ML	3740/22T	023237	IASIS PHARMACEUTICALS HELLAS SA	B.II.e.5.d B.II.e.5.d - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products
GABAPENTIN ACCORD CAPSULE, HARD 400MG	5156/21T, 5157/21T	022567	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
GABAPENTIN ACCORD CAPSULE, HARD 300MG	5154/21T, 5155/21T	022566	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place

ISOTROIN CAPSULE, SOFT 20MG	3805/22T	020693	IASIS PHARMACEUTICALS HELLAS SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ISOTROIN CAPSULE, SOFT 10MG	3804/22T	020695	IASIS PHARMACEUTICALS HELLAS SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CHLOROQUINE PHOSPHATE TABLET, COATED 250MG	2333/22T	012096	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority
MYDOFLEX TABLET, FILM COATED 150MG	3437/22T, 3438/22T	016780	M K STAVRINOS LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.d.1.b.1 B.I.d.1.b.1 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Storage conditions - Change to more restrictive storage conditions of the active substance
CARDILOR TABLET 200MG	8395/21T	009126	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under

				Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CARDILOR TABLET 200MG	2257/22T	009126	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
BINOSTO EFFERVESCENT TABLET 70MG	5510/21T	023029	GALENICA SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BUSCOFEM EXTRA TABLET, FILM COATED 400MG/100MG	9888/20T	023552	SANOFI AVENTIS AEBE	A.2 b) for Nationally Authorised Products
ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 10MG	7864/20T	null	SANDOZ GMBH	A.1 Change in the name and/or address of the marketing authorisation holder
ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 40MG	7862/20T	null	SANDOZ GMBH	A.1 Change in the name and/or address of the marketing authorisation holder
ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 20MG	7863/20T	null	SANDOZ GMBH	A.1 Change in the name and/or address of the marketing authorisation holder
IMATINIB SANDOZ TABLET, FILM COATED 100MG	7867/20T	null	SANDOZ GMBH	A.1 Change in the name and/or address of the

				marketing authorisation holder
ROSUVASTATIN CALCIUM SANDOZ TABLET, FILM COATED 5MG	7865/20T	null	SANDOZ GMBH	A.1 Change in the name and/or address of the marketing authorisation holder
EZETIMIBE SANDOZ TABLET 10MG	7872/20T	022118	SANDOZ GMBH	A.1 Change in the name and/or address of the marketing authorisation holder
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 18MG	7871/20T	021505	SANDOZ GMBH	A.1 Change in the name and/or address of the marketing authorisation holder
EFAVIRENZ SANDOZ TABLET, FILM COATED 600MG	7868/20T	021958	SANDOZ GMBH	A.1 Change in the name and/or address of the marketing authorisation holder
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 36MG	7870/20T	021506	SANDOZ GMBH	A.1 Change in the name and/or address of the marketing authorisation holder
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 54MG	7869/20T	021507	SANDOZ GMBH	A.1 Change in the name and/or address of the marketing authorisation holder
IMATINIB SANDOZ TABLET, FILM COATED 400MG	7866/20T	null	SANDOZ GMBH	A.1 Change in the name and/or address of the marketing authorisation holder
CAPOLEV PLUS TABLET 32/25MG	3946/22T	021613	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
CAPOLEV PLUS TABLET 16/12.5MG	3944/22T	021611	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
CAPOLEV PLUS TABLET 8/12.5MG	3943/22T	021610	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
CAPOLEV PLUS TABLET 32/12.5MG	3945/22T	021612	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 4MMOL/L	4119/21T	021045	GAMBRO LUNDIA AB	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 2MMOL/L	4118/21T	021044	GAMBRO LUNDIA AB	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 4MMOL/L	1673/20T, 1674/20T, 1675/20T, 1676/20T, 1677/20T, 1678/20T, 1679/20T, 1680/20T, 1681/20T	021045	GAMBRO LUNDIA AB	B.II.d.2 d) Other changes to a test procedure (including replacement or addition) B.II.b.4 a) Up to 10-fold compared to the originally approved batch size B.II.b.3 z) Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product Other variation B.II.b.2 c) 2. Including batch control/testing B.II.b.1 f) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured)

				excluding biological/ immunological medicinal products
PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 2MMOL/L	1682/20T, 1683/20T, 1684/20T, 1685/20T, 1686/20T, 1687/20T, 1688/20T, 1689/20T, 1690/20T	021044	GAMBRO LUNDIA AB	B.II.d.2 d) Other changes to a test procedure (including replacement or addition) B.II.b.4 a) Up to 10-fold compared to the originally approved batch size B.II.b.3 z) Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product Other variation B.II.b.2 c) 2. Including batch control/testing B.II.b.1 f) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products
AMLORINE 10 TABLET 10MG	1104/22T, 1105/22T, 1106/22T, 1107/22T, 1108/22T	020259	REMEDICA LTD	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a

				national pharmacopoeia of a Member State - Change to comply with an update of the relevant monogra B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat
AMLORINE 5 TABLET 5MG	1099/22T, 1100/22T, 1101/22T, 1102/22T, 1103/22T	020258	REMEDICA LTD	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph.

				Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monogra B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where bat
BICOL TABLET, FILM COATED 6.25MG	3976/22T	021340	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
BICOL TABLET, FILM COATED 25MG	3978/22T	021342	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT -

				Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
BICOL TABLET, FILM COATED 12.5MG	3977/22T	021341	DELORBIS PHARMACEUTICALS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ALOPRON TABLET 300MG	3953/22T	019954	REMEDICA LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ALOPRON TABLET 100MG	3954/22T	019700	REMEDICA LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ALOPRON TABLET 300MG	1303/22T, 1304/22T, 1305/22T, 1306/22T, 1307/22T	019954	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w
ALOPRON TABLET 100MG	1308/22T, 1309/22T, 1310/22T, 1311/22T, 1312/22T	019700	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w
MYDRANE SOLUTION FOR INJECTION 0.2MG/ML+3.1MG/ML+10MG/ML	3526/21T	022523	LABORATOIRES THEA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CATAFLAM TABLET, COATED 50MG	3899/22T	018492	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
NIFELAT LA TABLET, PROLONGED-RELEASE 60MG	2969/22T	020355	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NIFELAT LA TABLET, PROLONGED-RELEASE 30MG	2968/22T	020354	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZINNAT TABLET, FILM COATED 500MG	9358/21T	016847	GLAXOSMITHKLINE (IRELAND) LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ZINNAT TABLET, FILM COATED 250MG	9357/21T	016846	GLAXOSMITHKLINE (IRELAND) LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ZINNAT GRANULES FOR ORAL SUSPENSION 250MG/5ML	9356/21T	018086	GLAXOSMITHKLINE (IRELAND) LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
FORADIL INHALATION POWDER, HARD CAPSULE 12MCG	2880/22T, 2881/22T, 2882/22T, 2883/22T, 2884/22T, 2885/22T, 2886/22T, 2887/22T	018494	NOVARTIS IRELAND LIMITED	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/int

				ermediate used in the manufacturing process of the active substance - Other changes B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes
ACCUPRON TABLET, FILM COATED 20MG	2369/22T	013096	PFIZER HELLAS AE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product

				Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ACCUPRON TABLET, FILM COATED 5MG	2368/22T	013095	PFIZER HELLAS AE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ROTEQ TABLET, FILM COATED 2MG	3498/22T	021540	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the

				provisions of an updated general monograph of the Ph. Eur for the finished product*
ROTEQ TABLET, FILM COATED 5MG	3499/22T	021543	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
ROTEQ TABLET, FILM COATED 1MG	3497/22T	021539	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
ROTEQ TABLET, FILM COATED 0.25MG	3495/22T	021537	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
ROTEQ TABLET, FILM COATED 0.5MG	3496/22T	021538	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT -

				Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
VIBRAMYCIN TABLET, DISPERSIBLE 100MG	3255/22T	013023	PFIZER HELLAS AE	B.II.a.3.a.1 B.II.a.3.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Addition , deletion or replacement
TRINISTEM TABLET, FILM COATED 600MG/200MG/245MG	2229/22T	022699	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
NOVOFEN TABLET 10MG	3156/22T	009123	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NOVOFEN TABLET 20MG	3155/22T	019918	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GLYCERYL TRINITRATE STERILE CONCENTRATE 5MG/ML	1806/22T	013817	PFIZER HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or

				Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
STREPFEN ORANGE SUGAR FREE LOZENGE 8.75MG	10510/20T	021793	RECKITT BENCKISER HELLAS CHEMICAL ABEE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BETAHISTINE AUROBINDO TABLET 8MG	2987/20T	023303	AUROBINDO PHARMA (MALTA) LIMITED	A.2 b) for Nationally Authorised Products
BETAHISTINE AUROBINDO TABLET 8MG	11078/20T	023303	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
LOFOTO EYE DROPS, SUSPENSION	1194/22T	017820	RAFARM S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANESTEN VAGINAL TABLET 500MG	3216/22T	023091	BAYER HELLAS ABEE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient

				(when mentioned in the dossier)*
HEXALEN OROMUCOSAL SOLUTION 5MG/5ML	3210/22T, 3211/22T	006685	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTISET CUTANEOUS SOLUTION	3208/22T	022083	T.C.CHRISTOFOROU LTD.	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
OCTISET VAGINAL SOLUTION	3207/22T	022084	T.C.CHRISTOFOROU LTD.	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the

				active substance - Minor change in the manufacturing process of the active substance
BRADIREM TABLET, FILM COATED 5MG	3440/22T	022611	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
BRADIREM TABLET, FILM COATED 7.5MG	3441/22T	022612	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
INSPRA TABLET, FILM COATED 50MG	7612/20T	020104	UPJOHN HELLAS LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
INSPRA TABLET, FILM COATED 25MG	7613/20T	020103	UPJOHN HELLAS LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
TRISEQUENS TABLET, FILM COATED	1209/22T	013501	NOVO NORDISK HELLAS LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
DUMOZOL TABLET, FILM COATED 500MG	3706/22T	009720	ACTAVIS GROUP PTC EHF	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DUMOZOL TABLET, FILM COATED 250MG	3705/22T	009719	ACTAVIS GROUP PTC EHF	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
OPTODROP-CO EYE DROPS, SOLUTION (2+0.5)%	2346/22T	020546	RAFARM S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ANALGISER TABLET 500MG	3806/22T	010052	CODAL SYNTO LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LAMISIL CREAM 1%	8104/21T, 8105/21T	018386	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TROVAL TABLET, FILM COATED 40MG	1850/22T	022510	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a

				new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TROVAL TABLET, FILM COATED 160MG	1852/22T	021334	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TROVAL TABLET, FILM COATED 80MG	1851/22T	021333	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TOBREX EYE DROPS 0.3% W/V	834/22T	017322	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MEROSAP POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/VIAL	1014/22T	023498	SAPIENS PHARMACEUTICALS LTD	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product
MEROSAP POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	1013/22T	023085	SAPIENS PHARMACEUTICALS LTD	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED

				PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product
VENTOLIN EVOHALER AEROSOL 100MCG/DOSE	9791/21T	018619	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VACONTIL TABLET 2MG	3476/22T	021022	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OFLOXIN TABLET, FILM COATED 200MG	3515/22T	014408	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
OFLOXIN TABLET, FILM COATED 400MG	3516/22T	019793	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CANDIPLAS CREAM 2% W/W	1875/22T	019935	MEDOCHEMIE LTD	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
ILGEM SHAMPOO 20MG/G	1874/22T	016852	COSTAKIS TSISIOS & CO. LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MOVATEC TABLET 15MG	3242/22T	019616	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
MOVATEC TABLET 7.5MG	3241/22T	019617	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
MAALOX PLUS ORAL SUSPENSION	2098/21T	019265	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
BRONCOTERIL INHALATION POWDER, HARD CAPSULE 12MCG	3104/22T	020576	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
ONCOTICE POWDER FOR SOLUTION FOR INFUSION	3295/22T	019017	MSD AFVEE	B.II.b.2.b B.II.b.2.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method
HALOXEN TABLET 10MG	3463/22T, 3464/22T, 3465/22T, 3466/22T, 3467/22T	016307	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w
HALOXEN 20 TABLET 20MG	3458/22T, 3459/22T, 3460/22T, 3461/22T, 3462/22T	010437	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change

				to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w
HALOXEN TABLET 5MG	3453/22T, 3454/22T, 3455/22T, 3456/22T, 3457/22T	008589	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national

				pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w
AGREGEX TABLET, FILM COATED 75MG	3439/22T	20666	ACTAVIS GROUP PTC EHF	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
VIBRAMYCIN TABLET, DISPERSIBLE 100MG	3194/22T	013023	PFIZER HELLAS AE	B.III.2.c B.III.2.c - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur.
STREPFEN DIRECT CHERRY & MINT OROMUCOSAL SPRAY 8.75MG	10228/20T	022717	RECKITT BENCKISER HELLAS CHEMICAL ABEE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
STREPFEN DIRECT CHERRY & MINT OROMUCOSAL SPRAY 8.75MG	7290/20T, 7291/20T, 7292/20T, 7293/20T, 7294/20T, 7295/20T, 7296/20T, 7297/20T, 7298/20T, 7299/20T, 7300/20T, 7301/20T,	022717	RECKITT BENCKISER HELLAS CHEMICAL ABEE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation A.2 b) for Nationally

	7302/20T, 7303/20T, 7304/20T			Authorised Products
IMMUNATE 1000 IU FVIII/750 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/10ML	8229/20T	020086	BAXALTA INNOVATIONS GMBH	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
IMMUNATE 500 IU FVIII/375 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/5ML	8230/20T	020085	BAXALTA INNOVATIONS GMBH	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
IMMUNATE 250 IU FVIII/190 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250IU/5ML	8231/20T	020084	BAXALTA INNOVATIONS GMBH	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
TOBI SOLUTION FOR INHALATION 300MG/5ML	3061/22T, 3062/22T, 3063/22T	019439	MYLAN IRE HEALTHCARE LIMITED	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes
BICOL TABLET, FILM COATED 12.5MG	1533/22T	021341	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BICOL TABLET, FILM COATED 25MG	1534/22T	021342	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BORTEZOMIB VENUS PHARMA POWDER FOR SOLUTION FOR INJECTION 3.5MG/VIAL	8614/21T, 8615/21T	023489	STAR PHARMASIN LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.z A.z - ADMINISTRATIVE

				CHANGES - Other variation
MONOCLOX POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG	2962/22T, 2963/22T, 2964/22T	021025	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MONOCLOX POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	2965/22T, 2966/22T, 2967/22T	021026	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MONOCLOX POWDER FOR SOLUTION FOR INJECTION/INFUSION 250MG	2959/22T, 2960/22T, 2961/22T	021024	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CRESTOR TABLET, FILM COATED 5MG	3112/22T	019728	ASTRAZENECA AB	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
CRESTOR TABLET, FILM COATED 10MG	3113/22T	019622	ASTRAZENECA AB	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet

				intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
CRESTOR TABLET, FILM COATED 20MG	3114/22T	019623	ASTRAZENECA AB	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
CRESTOR TABLET, FILM COATED 40MG	3115/22T	019624	ASTRAZENECA AB	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ISOPTO-MAXITROL EYE DROPS, SUSPENSION	760/22T	017328	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LUCIDEL TABLET, FILM COATED 75MG	2220/22T	021869	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LUCIDEL TABLET, FILM COATED 150MG	2221/22T	021870	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LUCIDEL TABLET, FILM COATED 300MG	2222/22T	021871	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LUCIDEL PLUS TABLET, FILM COATED (300+12.5)MG	2218/22T	022180	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LUCIDEL PLUS TABLET, FILM COATED (300+25)MG	2217/22T	022181	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
LUCIDEL PLUS TABLET, FILM COATED (150+12.5)MG	2219/22T	022179	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the

				active substance - Minor changes to an approved test procedure
ISOPTO-MAXITROL EYE OINTMENT	715/22T	017327	NOVARTIS IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GISOLOM PLUS EYE DROPS, SOLUTION (50MCG/5MG)/ML	1843/22T	022355	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

LAMOSYNT TABLET 200MG	2214/22T	021490	CODAL-SYNTO LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
LAMOSYNT TABLET 25MG	2211/22T	021487	CODAL-SYNTO LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*

LAMOSYNT TABLET 50MG	2212/22T	021488	CODAL-SYNTO LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
LAMOSYNT TABLET 100MG	2213/22T	021489	CODAL-SYNTO LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*

CARDURA TABLET 4MG	3130/22T	017364	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CARDURA TABLET 2MG	3129/22T	017363	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
FRAXIPARINE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 5700IU AXa/0.6ML	2377/22T	019117	MYLAN IRE HEALTHCARE LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FRAXIPARINE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 2850IU AXa/0.3ML	2376/22T	019116	MYLAN IRE HEALTHCARE LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REMINYL ORAL SOLUTION 5.127MG/ML(4MG/ML)	3508/22T	019543	JANSSEN-CILAG INTERNATIONAL NV	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DUPHALAC ORAL SOLUTION 3.335G/5ML	3506/22T	007547	MYLAN IRE HEALTHCARE LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CANDIPLAS H CREAM	1580/22T	012705	MEDOCHE MIE LTD	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
CAVERIL TABLET, COATED 80MG	3119/22T, 3120/22T, 3121/22T, 3122/22T, 3123/22T	008938	REMEDICA LTD	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation

CAVERIL TABLET, COATED 40MG	3124/22T, 3125/22T, 3126/22T, 3127/22T, 3128/22T	008937	REMEDICA LTD	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
SEVELAMER LEDPHARM TABLET, FILM COATED 800MG	968/20T, 969/20T	022733	O.S.K. LEDPHARM LTD	A.2 b) for Nationally Authorised Products C.I.8 a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
TRAV-IOP PRESERVATIVE FREE EYE DROPS, SOLUTION 0.004% W/V	3064/22T, 3065/22T	023067	VERISFIELD SINGLE MEMBER S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the

				manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
BATRAFEN MEDICATED NAIL LACQUER 8% W/W	3245/22T	016139	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROPRAMIN TABLET, FILM COATED 40MG	3266/22T	020743	IASIS PHARMACEUTICALS HELLAS SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics,

				Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ROPRAMIN TABLET, FILM COATED 20MG	3265/22T	020742	IASIS PHARMACEUTICALS HELLAS SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
TRAVOCORT CREAM	8490/17T	019603	LEO PHARMA A/S	C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority*
DEPAKINE CHRONO TABLET, PROLONGED-RELEASE 500MG	2317/21T	019172	SANOFI-AVENTIS GROUPE	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which

				require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
BEGALIN-P POWDER FOR SOLUTION FOR INJECTION (1G/2G)/VIAL	1168/22T	013278	PFIZER HELLAS AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	2797/20T	019161	SANOFI-AVENTIS GROUPE	C.I.6 a) Addition of a new therapeutic indication or modification of an approved one
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	2799/20T	019160	SANOFI-AVENTIS GROUPE	C.I.6 a) Addition of a new therapeutic indication or modification of an approved one
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	2800/20T	019159	SANOFI-AVENTIS GROUPE	C.I.6 a) Addition of a new therapeutic indication or modification of an approved one
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	2798/20T	019744	SANOFI-AVENTIS GROUPE	C.I.6 a) Addition of a new therapeutic indication or modification of an approved one
METHOTREXATE/PFIZER TABLET 2.5MG	2502/21T, 2503/21T	002904	PFIZER HELLAS AE	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the

				name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
BIOSONIDE NEBULISER SUSPENSION 1MG/2ML	2339/22T, 2340/22T, 2341/22T, 2342/22T, 2343/22T	023137	HELP S.A.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)

				B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
BIOSONIDE NEBULISER SUSPENSION 0.5MG/2ML	2334/22T, 2335/22T, 2336/22T, 2337/22T, 2338/22T	023136	HELP S.A.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a

				specification parameter with its corresponding test method as a result of a safety or quality issue B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
PAZOCTAM POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/ VIAL	1214/22T, 1215/22T, 1216/22T, 1217/22T, 1218/22T, 1219/22T, 1220/22T, 1221/22T, 1222/22T, 1223/22T, 1224/22T, 1225/22T, 1226/22T, 1227/22T, 1228/22T, 1229/22T, 1230/22T, 1231/22T, 1232/22T, 1233/22T, 1234/22T, 1235/22T, 1236/22T, 1237/22T, 1238/22T, 1239/22T, 1240/22T, 1241/22T, 1242/22T, 1243/22T, 1244/22T, 1245/22T, 1246/22T, 1247/22T, 1248/22T, 1249/22T, 1250/22T, 1251/22T	022811	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TS B.I.a.1.c B.I.a.1.c - QUALITY CHANGES - ACTIVE SUB B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED B.II.e.4.c B.II.e.4.c - QUALITY CHANGES - FINISHED B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED B.II.e.1.a.3 B.II.e.1.a.3 - QUALITY CHANGES - FINI B.III.2.z B.III.2.z - QUALITY

				CHANGES - CEP/TSE/MO B.II.b.4.d B.II.b.4.d - QUALITY CHANGES - FINISHED B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED
NU-SEALS TABLET, GASTRO-RESISTANT 75MG	9525/21T	016122	PHADISCO LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
EPIBAL CAPSULE, HARD 75MG	2972/22T	022807	DELORBIS PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
EPIBAL CAPSULE, HARD 50MG	2971/22T	022806	DELORBIS PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
EPIBAL CAPSULE, HARD 25MG	2970/22T	022805	DELORBIS PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal

				recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
EPIBAL CAPSULE, HARD 150MG	2973/22T	022808	DELORBIS PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PIRAZOL TABLET 15MG	2289/22T	022879	CODAL-SYNTO LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
PIRAZOL TABLET 10MG	2288/22T	022878	CODAL-SYNTO LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
PIRAZOL TABLET 5MG	2287/22T	022877	CODAL-SYNTO LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
PIRAZOL TABLET 30MG	2291/22T	022881	CODAL-SYNTO LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
PIRAZOL TABLET 20MG	2290/22T	022880	CODAL-SYNTO LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	2774/22T	020564	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product

BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	2775/22T	022321	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	2776/22T	023120	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	2777/22T	023121	CSL BEHRING GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new,

				updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
DOXAT TABLET, FILM COATED 100MG	1846/22T	014668	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
RILCAPTON TABLET 50MG	2326/22T	020020	MEDOCHEMIE LTD	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
RILCAPTON TABLET 25MG	2325/22T	011053	MEDOCHEMIE LTD	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph.

				Eur. or with a national pharmacopoeia of a Member State - Active substance
MOXILEN CAPSULE, HARD 250MG	2263/22T, 2264/22T, 2265/22T, 2266/22T	007236	MEDOCHE MIE LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monogr B.II.d.1.i B.II.d.1.i - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Ph. Eur. 2.9.40 Uniformity of dosage units is introduced to replace the currentl B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
MOXILEN CAPSULE, HARD 500MG	2267/22T, 2268/22T, 2269/22T, 2270/22T	007237	MEDOCHE MIE LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monogr B.II.d.1.i B.II.d.1.i - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Ph. Eur. 2.9.40 Uniformity of dosage units is introduced to replace the currentl B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
MEMINI TABLET, FILM COATED 20MG	486/22T	022340	ELPEN PHARMACEUTICAL CO INC	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MEMINI TABLET, FILM COATED 10MG	485/22T	022339	ELPEN PHARMACEUTICAL CO INC	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATARAX SYRUP 2MG/ML	2347/22T	000315	UCB PHARMA SA	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
IMAREM TABLET, FILM COATED 100MG	2259/22T	021689	REMEDICA LTD	C.z C.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - Other variation C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
IMAREM TABLET, FILM COATED 400MG	2260/22T	021690	REMEDICA LTD	C.z C.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Other variation C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
IMATINIB REMEDICA TABLET, FILM COATED 400MG	2345/22T	021688	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
IMATINIB REMEDICA TABLET, FILM COATED 100MG	2344/22T	021687	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CLOVELEN TABLET, FILM COATED 75MG	3286/22T, 3287/22T	021076	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
CLOVELEN TABLET, FILM COATED 75MG	1208/22T	021076	ELPEN PHARMACEUTICAL CO INC	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
IDARUBICIN ACCORD SOLUTION FOR INJECTION 10MG/10ML	1293/21T	023260	ACCORD HEALTHCARE S.L.U	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	1291/21T	023259	ACCORD HEALTHCARE S.L.U	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of

				change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	1292/21T	023261	ACCORD HEALTHCARE S.L.U	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
CLARITYNE-D TABLET, PROLONGED-RELEASE 5MG/120MG	3274/22T	016294	BAYER HELLAS ABEE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
PIRIGLIM TABLET 2MG	1640-1641/17T, 679/22T, 680/22T, 681/22T, 682/22T, 683/22T	021622	CODAL-SYNTO LIMITED	B.III.1 a) 2. Updated certificate from an already approved manufacturer Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or

				supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PIRIGLIM TABLET 3MG	1642-1643/17T, 684/22T, 685/22T, 686/22T, 687/22T, 688/22T	021623	CODAL-SYNTO LIMITED	B.III.1 a) 2. Updated certificate from an already approved manufacturer Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PIRIGLIM TABLET 4MG	1644-1645/17T, 689/22T, 690/22T, 691/22T, 692/22T, 693/22T	021624	CODAL-SYNTO LIMITED	B.III.1 a) 2. Updated certificate from an already approved manufacturer Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PIRIGLIM TABLET 1MG	1638-1639/17T, 674/22T, 675/22T, 676/22T, 677/22T, 678/22T	021621	CODAL-SYNTO LIMITED	B.III.1 a) 2. Updated certificate from an already approved manufacturer Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material,

				reagent or excipient (when mentioned in the dossier)*
FORADIL INHALATION POWDER, HARD CAPSULE 12MCG	2365/22T	018494	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
ALBUREX 5 SOLUTION FOR INFUSION 50G/L	7518/20T	20629	CSL BEHRING GMBH	B.V.a.1 d) Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	7517/20T	20630	CSL BEHRING GMBH	B.V.a.1 d) Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUREX 5 SOLUTION FOR INFUSION 50G/L	1970/21T, 1971/21T	20629	CSL BEHRING GMBH	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test

				procedure B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	1972/21T, 1973/21T	20630	CSL BEHRING GMBH	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ALBUREX 5 SOLUTION FOR INFUSION 50G/L	3675/21T	20629	CSL BEHRING GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	3676/21T	20630	CSL BEHRING GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to

				an approved test procedure
ALBUREX 5 SOLUTION FOR INFUSION 50G/L	4162/21T, 4163/21T	20629	CSL BEHRING GMBH	B.I.z B.I.z - Quality change - Active substance - Other variation B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	4164/21T, 4165/21T	20630	CSL BEHRING GMBH	B.I.z B.I.z - Quality change - Active substance - Other variation B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
NETIN CAPSULE, HARD 400MG	3144/22T	021186	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
NETIN CAPSULE, HARD 100MG	3142/22T	021184	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
NETIN CAPSULE, HARD 300MG	3143/22T	021185	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CLOXACILLIN CAPSULE, HARD 500MG	1524/22T, 1525/22T, 1526/22T, 1527/22T	018356	REMEDICA LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or

				supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
CLOXACILLIN CAPSULE, HARD 250MG	1520/22T, 1521/22T, 1522/22T, 1523/22T	009135	REMEDICA LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2

				- QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
INTRATECT SOLUTION FOR INFUSION 100G/L	1966/21T	022263	BIOTEST PHARMA GMBH	B.II.b.4.f B.II.b.4.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line)
INTRATECT SOLUTION FOR INFUSION 50G/L	1967/21T	021466	BIOTEST PHARMA GMBH	B.II.b.4.f B.II.b.4.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the

				batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line)
FLUOXETINE AUROBINDO CAPSULE, HARD 20MG	7953/20T	023333	AUROBINDO PHARMA (MALTA) LIMITED	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
FLUOXETINE AUROBINDO CAPSULE, HARD 20MG	11393/20T	023333	AUROBINDO PHARMA (MALTA) LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
AMLOBE TABLET 10MG	2379/22T	021193	TAD PHARMA GMBH	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
AMLOBE TABLET 5MG	2378/22T	021192	TAD PHARMA GMBH	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
FORADIL INHALATION POWDER, HARD CAPSULE 12MCG	2184/22T, 2185/22T	018494	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
ZADITEN EYE DROPS, SOLUTION 0.25MG/ML	3102/22T, 3103/22T	019261	LABORATOIRES THEA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ADVECIT CAPSULE, HARD 5MG	1174/22T	021445	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ADVECIT CAPSULE, HARD 20MG	1173/22T	021446	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ADVECIT CAPSULE, HARD 140MG	1171/22T	021448	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ADVECIT CAPSULE, HARD 250MG	1169/22T	021450	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer

				(replacement or addition)
ADVECIT CAPSULE, HARD 180MG	1170/22T	021449	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ADVECIT CAPSULE, HARD 100MG	1172/22T	021447	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
SYNTOSARTIN TABLET 300MG	8503/21T, 8504/21T	020977	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SYNTOSARTIN TABLET 150MG	8501/21T, 8502/21T	020976	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SYNTOSARTIN TABLET 75MG	8499/21T, 8500/21T	020975	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SYNTOSARTIN PLUS TABLET, FILM COATED 150MG/12.5MG	8630/21T, 8631/21T	022199	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SYNTOSARTIN PLUS TABLET, FILM COATED 300MG/25MG	8626/21T, 8627/21T	022201	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SYNTOSARTIN PLUS TABLET, FILM COATED 300MG/12.5MG	8628/21T, 8629/21T	022200	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MAALOX ORAL SUSPENSION (22.8+40)MG/ML	1777/22T	019266	SANOFI - AVENTIS CYPRUS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
MAALOX PLUS ORAL SUSPENSION	1587/22T	019265	SANOFI - AVENTIS CYPRUS LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for

				the finished product - Minor changes to an approved test procedure
SYNTOCEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	1360/22T, 1361/22T	021191	CODAL SYNTO LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
BUSCOPAN PLUS TABLET, FILM COATED	9354/21T	014583	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MAALOX ORAL SUSPENSION (22.8+40)MG/ML	5911/21T	019266	SANOFI - AVENTIS CYPRUS LTD	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes
SEVELAMER CARBONATE SANDOZ TABLET, FILM COATED 800MG	7488/20T	022154	SANDOZ GMBH	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ARCOXIA TABLET, FILM COATED 60MG	4835/21T	019444	MERCK SHARP & DOHME BV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation

ARCOXIA TABLET, FILM COATED 120MG	4837/21T	019446	MERCK SHARP & DOHME BV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ARCOXIA TABLET, FILM COATED 90MG	4836/21T	019445	MERCK SHARP & DOHME BV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AVERNOL TABLET 25MG	914/22T	020151	MEDOCHE MIE LTD	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
VACONTIL CAPSULE, HARD 2MG	2384/22T	008524	MEDOCHE MIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
ISOTROIN CAPSULE, SOFT 30MG	2364/22T	023420	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ISOTROIN CAPSULE, SOFT 20MG	2360/22T	020693	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

ISOTROIN CAPSULE, SOFT 10MG	2359/22T	020695	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VIZITRAV EYE DROPS, SOLUTION 40MCG/ML	7215/21T	023221	BAUSCH HEALTH IRELAND LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DYSPORT POWDER FOR SOLUTION FOR INJECTION 500U	1399/22T	019337	IPSEN M.E.P.E.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
NOOTROPIL ORAL SOLUTION 200MG/ML	2216/22T	007087	UCB PHARMA SA	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or

				limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
HYALGAN SOLUTION FOR INJECTION 20MG/2ML	1582/22T, 1583/22T, 1584/22T	019609	MULTI-PHARM CO LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised
TREVUSIN CAPSULE, HARD 8MG	1818/22T	023388	DELORBIS PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TREVUSIN CAPSULE, HARD 4MG	1817/22T	023387	DELORBIS PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
RITHROCLAD TABLET, FILM COATED 500MG	1845/22T	021791	CODAL-SYNTO LIMITED	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification

				parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits
RITHROCLAD TABLET, FILM COATED 250MG	1844/22T	021790	CODAL-SYNTO LIMITED	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits
LAMOTRIX TABLET 50MG	8467/21T, 8468/21T	018538	MEDOCHEMIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the

				finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LAMOTRIX TABLET 100MG	8471/21T, 8472/21T	018541	MEDOCHE MIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LAMOTRIX TABLET 25MG	8473/21T, 8474/21T	018540	MEDOCHE MIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the

				finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LAMOTRIX TABLET 200MG	8469/21T, 8470/21T	018539	MEDOCHE MIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and

				quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
CANESTEN CUTANEOUS SOLUTION 1%	1175/22T	023099	BAYER HELLAS ABEE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
ALIMAX TABLET 80MG	2300/22T, 2301/22T	021343	DELORBIS PHARMACEUTICALS LTD	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALIMAX TABLET 40MG	2298/22T, 2299/22T	021338	DELORBIS PHARMACEUTICALS LTD	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMOTRIX TABLET 50MG	476/22T	018538	MEDOCHEMIE LTD	B.II.d.1.h B.II.d.1.h -

				QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
LAMOTRIX TABLET 100MG	477/22T	018541	MEDOCHE MIE LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
LAMOTRIX TABLET 200MG	478/22T	018539	MEDOCHE MIE LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
LAMOTRIX TABLET 25MG	475/22T	018540	MEDOCHE MIE LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to

				comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
BEZANIN TABLET, FILM COATED 500MG	2197/22T	020894	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
CLAREM TABLET, FILM COATED 500MG	8862/21T	019181	REMEDICA LTD	C.z C.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Other variation
CLAREM TABLET, FILM COATED 250MG	8861/21T	019180	REMEDICA LTD	C.z C.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Other variation
CLAREM TABLET, FILM COATED 250MG	8809/21T, 8810/21T, 8811/21T, 8812/21T, 8813/21T, 8814/21T, 8815/21T, 8816/21T, 8817/21T, 8818/21T, 8819/21T, 8820/21T, 8821/21T, 8822/21T, 8823/21T, 8824/21T, 8825/21T, 8826/21T, 8827/21T, 8828/21T, 8829/21T, 8830/21T, 8831/21T, 8832/21T, 8833/21T, 8834/21T	019180	REMEDICA LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submis B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.e.1.a.1

				B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Contai B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.a.3.b.5 B.II.a.3.b.5 - QUALITY CHANGES - FINISHED PRODUCT - Descri
CLAREM TABLET, FILM COATED 500MG	8835/21T, 8836/21T, 8837/21T, 8838/21T, 8839/21T, 8840/21T,	019181	REMEDICA LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY

	8841/21T, 8842/21T, 8843/21T, 8844/21T, 8845/21T, 8846/21T, 8847/21T, 8848/21T, 8849/21T, 8850/21T, 8851/21T, 8852/21T, 8853/21T, 8854/21T, 8855/21T, 8856/21T, 8857/21T, 8858/21T, 8859/21T, 8860/21T			CHANGES - CEP/TSE/MONOGRAPHS - Submis B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Contai B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT -

				Manufactur B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Manufactur B.II.a.3.b.5 B.II.a.3.b.5 - QUALITY CHANGES - FINISHED PRODUCT - Descri
PARIET TABLET, GASTRO-RESISTANT 20MG	2231/22T	018888	JANSSEN-CILAG INTERNATIONAL NV	B.II.f.1.e B.II.f.1.e - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change to an approved stability protocol
PARIET TABLET, GASTRO-RESISTANT 10MG	2230/22T	018887	JANSSEN-CILAG INTERNATIONAL NV	B.II.f.1.e B.II.f.1.e - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change to an approved stability protocol
CANDIPLAS H CREAM	1579/22T	012705	MEDOCHEMIE LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
CANDEPRESS COMP TABLET 16MG/12.5MG	2191/22T	021739	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDEPRESS COMP TABLET 8MG/12.5MG	2190/22T	021738	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PONSTAN FORTE TABLET, FILM COATED 500MG	1659/20T	019500	PFIZER HELLAS AE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PONSTAN SYRUP 50MG/5ML	1658/20T	007531	PFIZER HELLAS AE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality,

				preclinical, clinical or pharmacovigilance data.
FELDENE GEL 0.5%	1657/20T	013022	PFIZER HELLAS AE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
ASPRO CLEAR EFFERVESCENT TABLET 300MG	11134/20T	022932	BAYER HELLAS ABEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ASPRO CLEAR EFFERVESCENT TABLET 300MG	7273/20T	022932	BAYER HELLAS ABEE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	2327/22T	021944	MEDOCHEMIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	2329/22T	019897	MEDOCHE MIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	2328/22T	019896	MEDOCHE MIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TEVETEN TABLET, FILM COATED 600MG	1774/22T, 1775/22T, 1776/22T	019260	MYLAN IRE HEALTHCAR E LIMITED	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Reduction in the testing frequency of an analysis, from routine testing to skip or periodic testing (microbial testing of finished product). B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for

				the finished product - Minor changes to an approved test procedure
ATROVENT NEBULISER SOLUTION 500MCG/2ML	59/22T	014215	BOEHRINGER INGELHEIM HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BEROVENT SOLUTION FOR INHALATION	58/22T	019532	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ATROVENT NEBULISER SOLUTION 250MCG/2ML	60/22T	019548	BOEHRINGER INGELHEIM HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LONARID N SUPPOSITORY (400+20+50) MG	56/22T	019679	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LONARID N TABLET (400+10+50) MG	55/22T	019678	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ATROVENT INHALATION SOLUTION, PRESSURISED 20MCG/DOSE	57/22T	019534	BOEHRINGER INGELHEIM HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PIRIGLIM TABLET 2MG	856/22T	021622	CODAL SYNTO LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PIRIGLIM TABLET 3MG	857/22T	021623	CODAL SYNTO LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

PIRIGLIM TABLET 4MG	858/22T	021624	CODAL SYNTO LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PIRIGLIM TABLET 1MG	855/22T	021621	CODAL SYNTO LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FEMOSTON TABLET, FILM COATED	2215/22T	017842	MYLAN IRE HEALTHCARE LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority.
FODREN TABLET, GASTRO-RESISTANT 20MG	1403/22T	021182	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
FODREN TABLET, GASTRO-RESISTANT 10MG	1402/22T	021181	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT -

				Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
SOLMUCOL SYRUP 20MG/ML	1213/22T	019527	IBSA FARMACEUTICI ITALIA SRL	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
GISOLOM EYE DROPS, SOLUTION 50MCG/ML	2274/22T	022356	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

PERAZONE 0.5 TABLET 0.5MG	256/22T	007727	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
DOXURAL PROLONGED RELEASE CAPSULES 150MG	2273/22T	021189	DELORBIS PHARMACEUTICALS LTD	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
DOXURAL PROLONGED RELEASE CAPSULES 75MG	2272/22T	021188	DELORBIS PHARMACEUTICALS LTD	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
DOXURAL PROLONGED RELEASE CAPSULES 37.5MG	2271/22T	021187	DELORBIS PHARMACEUTICALS LTD	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change

				in test procedure for an excipient - Minor changes to an approved test procedure
HEMOSOL B0 SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS	null	023511	BAXTER HOLDING B.V.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	7335/21T	023231	BAUSCH + LOMB IRELAND LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	7335/21T	023231	BAUSCH + LOMB IRELAND LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LEVOXACIN SOLUTION FOR INFUSION 5MG/ML	10261/20T	020749	SAPIENS PHARMACEUTICALS LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
VOLTAREN INJECTION 75MG/3ML	6491/21T, 6492/21T, 6493/21T, 6494/21T	018434	NOVARTIS IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient

				(when mentioned in the dossier)* B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.a.z B.II.a.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Other variation B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
SYNTOSARTIN PLUS TABLET, FILM COATED 150MG/12.5MG	1017/22T	022199	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent

				authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SYNTOSARTIN PLUS TABLET, FILM COATED 300MG/25MG	1016/22T	022201	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SYNTOSARTIN PLUS TABLET, FILM COATED 300MG/12.5MG	1015/22T	022200	CODAL-SYNTO LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of

				Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	9669/20T, 9670/20T, 9671/20T	022511	SANOFI PASTEUR.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	10753/20T, 10754/20T, 10755/20T, 10756/20T	022511	SANOFI PASTEUR.	B.II.d.2 c) Substantial change to, or replacement of, a biological/

				immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol B.II.d.1 e) Change outside the approved specifications limits range B.II.b.3 c) The product is a biological/immunological medicinal product and the change requires an assessment of comparability. B.II z) FINISHED PRODUCT Other variation
SNIP TABLET	9734/21T, 9735/21T, 9736/21T	020113	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FOLIRON TABLET, FILM COATED 100MG/0.35MG	1182/22T, 1183/22T, 1184/22T, 1185/22T	017550	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NETIN CAPSULE, HARD 400MG	2304/22T	021186	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to

				be submitted by the MAH
NETIN CAPSULE, HARD 100MG	2302/22T	021184	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
NETIN CAPSULE, HARD 300MG	2303/22T	021185	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VINBLASTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	1581/22T	012083	PFIZER HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
VINBLASTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	1562/22T	012083	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SODIUM CHLORIDE + GLUCOSE/BAXTER SOLUTION FOR INFUSION (0.9+5)% W/V	8769/21T	017014	BAXTER (HELLAS) EPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+100)MCG/DOSE	5931/20T, 5932/20T, 1338/22T, 1339/22T, 1340/22T	021399	ELPEN PHARMACEUTICAL CO INC	B.III.1 a) 2. Updated certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS -

				Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+500)MCG/DOSE	5927/20T, 5928/20T, 1332/22T, 1333/22T, 1334/22T	020862	ELPEN PHARMACEUTICAL CO INC	B.III.1 a) 2. Updated certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+250)MCG/DOSE	5929/20T, 5930/20T, 1335/22T, 1336/22T, 1337/22T	020861	ELPEN PHARMACEUTICAL CO INC	B.III.1 a) 2. Updated certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TEGRETOL SYRUP 100MG/5ML	1211/22T, 1212/22T	018450	NOVARTIS IRELAND LIMITED	B.IV.1.a.1 B.IV.1.a.1 - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking B.IV.1.z B.IV.1.z - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Other variation
BETAISODONA STANDARDISED SOLUTION 10% W/V	1778/22T, 1779/22T	019992	MUNDIPHARMA PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing

				takes place B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test
SEIZAL TABLET, DISPERSIBLE 100MG	1591/22T	021701	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SEIZAL TABLET, DISPERSIBLE 200MG	1592/22T	021702	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of

				change(s) for which no new additional data is required to be submitted by the MAH
SEIZAL TABLET, DISPERSIBLE 50MG	1590/22T	021700	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SEIZAL TABLET, DISPERSIBLE 5MG	1588/22T	021698	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SEIZAL TABLET, DISPERSIBLE 25MG	1589/22T	021699	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ZOVIRAX ORAL SUSPENSION 200MG/5ML	1180/22T	010431	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZESTORETIC TABLET	266/22T	013839	ATNAHS PHARMA NETHERLANDS B.V.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZEPILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	638/22T	012523	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZEPILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	639/22T	012771	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MEDOVIR TABLET 200MG	2192/22T	012781	MEDOCHE MIE LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
FELDENE TABLET, DISPERSIBLE 20MG	1660/20T	012074	PFIZER HELLAS AE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
FELDENE TABLET, DISPERSIBLE 10MG	1661/20T	012075	PFIZER HELLAS AE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
FELDENE TABLET, DISPERSIBLE 20MG	8426/20T	012074	PFIZER HELLAS AE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
FELDENE TABLET, DISPERSIBLE 10MG	8427/20T	012075	PFIZER HELLAS AE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation

FELDENE TABLET, DISPERSIBLE 20MG	8710/21T	012074	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SALOFALK TABLET, GASTRO-RESISTANT 500MG	854/22T	013056	DR. FALK PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BUSCOPAN SOLUTION FOR INJECTION 20MG/ML	724/22T, 725/22T, 726/22T	003121	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes

				B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
FOSRENOL TABLET, CHEWABLE 500MG	630/22T	020046	SHIRE PHARMACEUTICALS IRELAND LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
FOSRENOL TABLET, CHEWABLE 750MG	631/22T	020047	SHIRE PHARMACEUTICALS IRELAND LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BETAISODONA SCALP & SKIN CLEANSER SOLUTION 7.5% W/V	392/22T, 393/22T, 394/22T, 395/22T, 396/22T, 397/22T, 398/22T, 399/22T, 400/22T, 401/22T, 402/22T, 403/22T, 404/22T, 405/22T, 406/22T, 407/22T, 408/22T, 409/22T, 410/22T, 411/22T, 412/22T, 413/22T, 414/22T, 415/22T, 416/22T, 417/22T, 418/22T, 419/22T, 420/22T, 421/22T, 422/22T	012330	MUNDIPHARMA PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of man B.II.a.3.b.6 B.II.a.3.b.6 - QUALITY CHANGES - FINI B.II.a.3.b.1 B.II.a.3.b.1 - QUALITY CHANGES - FINI B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED

				B.II.c.2.z B.II.c.2.z - QUALITY CHANGES - FINISHED B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED B.II.e.1.z B.II.e.1.z - QUALITY CHANGES - FINISHED B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED B.II.a.3.b.2 B.II.a.3.b.2 - QUALITY CHANGES - FINI B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINI
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	3913/21T	020234	IBSA FARMACEUTICI ITALIA SRL	B.II.b.1.c B.II.b.1.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing

				operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	3912/21T	020233	IBSA FARMACEUTICI ITALIA SRL	B.II.b.1.c B.II.b.1.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes
ZOVIRAX CREAM 5% W/W	1181/22T	009376	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance

				For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AGREGEX TABLET, FILM COATED 75MG	2943/21T	20666	ACTAVIS GROUP PTC EHF	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
AGREGEX TABLET, FILM COATED 75MG	10230/20T	20666	ACTAVIS GROUP PTC EHF	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to

				be submitted by the MAH
CINNARON TABLET 25MG	428/22T, 429/22T	008557	REMEDICA LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
CINNARON CAPSULE, HARD 75MG	426/22T, 427/22T	011726	REMEDICA LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance

				For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
CILOX TABLET, FILM COATED 400MG	1786/22T	016037	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of

				wording agreed by the competent authority
CILOX TABLET, FILM COATED 200MG	1787/22T	014717	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
GRANOCYTE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 34MIU	6562/21T	019158	SANOFI-AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
KRATIUM SOLUTION FOR INJECTION OR INFUSION 10MG/2ML	928/22T	020767	MEDOCHEMIE LTD	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits
BETNOVATE CREAM 0.1% W/W	6503/21T	016788	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or

				addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
CUTIVATE CREAM 0.05%	6504/21T	016799	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
ZOVIRAX CREAM 5% W/W	6502/21T	009376	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
BETAISODONA SURGICAL SCRUB 7.5% W/V	345/22T, 346/22T, 347/22T, 348/22T, 349/22T, 350/22T, 351/22T, 352/22T, 353/22T, 354/22T, 355/22T, 356/22T, 357/22T, 358/22T, 359/22T, 360/22T, 361/22T, 362/22T, 363/22T, 364/22T, 365/22T, 366/22T, 367/22T, 368/22T, 369/22T, 370/22T, 371/22T, 372/22T, 373/22T, 374/22T	019861	MUNDIPHARMA PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manuf B.II.a.3.b.6 B.II.a.3.b.6 - QUALITY CHANGES - FINISH B.II.a.3.b.1 B.II.a.3.b.1 - QUALITY CHANGES - FINISH B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED P B.II.b.3.b B.II.b.3.b

				- QUALITY CHANGES - FINISHED P B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED P B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED P B.II.c.2.z B.II.c.2.z - QUALITY CHANGES - FINISHED P B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED P B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED P B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED P B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED P B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED P B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED P B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED P B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED P B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED P B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED P B.II.a.3.b.2 B.II.a.3.b.2 - QUALITY CHANGES - FINISH
LUCIDEL PLUS TABLET, FILM COATED (300+12.5)MG	1187/22T	022180	ELPEN PHARMACEUTICAL CO INC	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Inclusion of the statements of ADR reporting
LUCIDEL PLUS TABLET, FILM COATED (300+25)MG	1188/22T	022181	ELPEN PHARMACEUTICAL CO INC	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Inclusion of the statements of ADR reporting
LUCIDEL PLUS TABLET, FILM COATED (150+12.5)MG	1186/22T	022179	ELPEN PHARMACEUTICAL CO INC	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Inclusion of the statements of ADR reporting
DIVIDOL TABLET, COATED 10MG	1313/22T, 1314/22T	019675	REMEDICA LTD	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
OVA-MIT TABLET 50MG	1133/22T, 1134/22T	007874	REMEDICA LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial

				substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
FLECTOR TISSUGEL MEDICATED PLASTER 1%	10253/20T	020149	IBSA FARMACEUTICI ITALIA SRL	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
LASIX SOLUTION FOR INJECTION 20MG/2ML	4228/20T	019672	SANOFI-AVENTIS GROUPE	A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LASIX TABLET 40MG	6533/21T	019673	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LASIX SOLUTION FOR INJECTION 20MG/2ML	6532/21T	019672	SANOFI-AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BUSCOFEM CAPSULE, SOFT 400MG	6731/21T	022424	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
CEFUROXIME-SYNTO TABLET, FILM COATED 500MG	8038/21T	021582	CODAL-SYNTO LIMITED	B.II.a.z B.II.a.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Other variation
CEFUROXIME-SYNTO TABLET, FILM COATED 250MG	8037/21T	021581	CODAL-SYNTO LIMITED	B.II.a.z B.II.a.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Other variation
CEFUROXIME-SYNTO TABLET, FILM COATED 500MG	8036/21T	021582	CODAL-SYNTO LIMITED	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms
CEFUROXIME-SYNTO TABLET, FILM COATED 250MG	8035/21T	021581	CODAL-SYNTO LIMITED	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms
COTROVAL TABLET, FILM COATED 160/12.5MG	1854/22T	021328	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COTROVAL TABLET, FILM COATED 320/25MG	1857/22T	021331	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COTROVAL TABLET, FILM COATED 320/12.5MG	1856/22T	021330	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COTROVAL TABLET, FILM COATED 80/12.5MG	1853/22T	021327	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COTROVAL TABLET, FILM COATED 160/25MG	1855/22T	021329	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ELXEDA TABLET 15MG	1772/22T	022353	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ELXEDA TABLET 30MG	1773/22T	022354	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
ELXEDA TABLET 10MG	1771/22T	022352	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ARCOXIA TABLET, FILM COATED 60MG	7587/20T	019444	MERCK SHARP & DOHME BV	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
ARCOXIA TABLET, FILM COATED 120MG	7585/20T	019446	MERCK SHARP & DOHME BV	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
ARCOXIA TABLET, FILM COATED 90MG	7586/20T	019445	MERCK SHARP & DOHME BV	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
ZORMID EYE DROPS, SOLUTION 20MG/ML	1805/22T	022357	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosi

				milar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
CISPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	1593/22T	012087	PFIZER HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ACMOTREN CAPSULE, SOFT 20MG	1561/22T	020321	SAPIENS PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon

ACMOTREN CAPSULE, SOFT 10MG	1560/22T	020320	SAPIENS PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
STATEZOL TABLET, FILM COATED 40MG/10MG	1816/22T	023580	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
STATEZOL TABLET, FILM COATED 10MG/10MG	1813/22T	023578	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
STATEZOL TABLET, FILM COATED 5MG/10MG	1815/22T	023577	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
STATEZOL TABLET, FILM COATED 20MG/10MG	1814/22T	023579	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the

				same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
CHORIOMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	1341/22T	010247	IBSA FARMACEUTICI ITALIA SRL	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
MEZAVANT GASTRO-RESISTANT, PROLONGED RELEASE TABLETS 1200MG	623/22T	020250	SHIRE PHARMACEUTICALS IRELAND LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
EBRILON TABLET, FILM COATED 5MG	1519/22T	21965	MEDOCHEMIE LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	8111/21T	022603	BAXTER (HELLAS) EPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
GLUCOSE 5%/BAXTER (VIAFLO) SOLUTION FOR INFUSION 5% W/V	8113/21T	019767	BAXTER (HELLAS) EPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SODIUM CHLORIDE/BAXTER(VIAFLO) SOLUTION FOR INFUSION 0.9% W/V	8112/21T	020065	BAXTER (HELLAS) EPE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AZEPIUM SOLUTION FOR INJECTION OR INFUSION 10MG/2ML	1196/22T	021868	CODAL-SYNTO LIMITED	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits
NIMM TABLET 100MG	1531/22T, 1532/22T	017715	CODAL-SYNTO LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or

				finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAX-TAB TABLET, GASTRO-RESISTANT 5MG	1528/22T, 1529/22T, 1530/22T	019734	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition

				(excipients) of the finished product - Other changes
URACTONUM TABLET 100MG	1401/22T	008523	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
URACTONUM TABLET 25MG	1400/22T	006832	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
BETAHISTINE AUROBINDO TABLET 8MG	1701/22T	023303	AUROBINDO PHARMA (MALTA) LIMITED	A.2. b) for Nationally Authorised Products For commercial reasons Aurobindo Pharma Limited intends to market the Betahistine Aurobindo 8 mg/ 16 mg tablets in Ireland using "Vertigon 8 mg/16 mg tabl
CANESTEN VAGINAL TABLET 500MG	1195/22T	023091	BAYER HELLAS ABEE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
GYRABLOCK TABLET, FILM COATED 400MG	1558/22T, 1559/22T	011772	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BERMOXEL TABLET 600MG	1518/22T	019838	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
BRIMONTAL EYE DROPS, SOLUTION 0.2% W/V	1568/22T	023061	RAFARM S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CALCIUM LACTATE TABLET 300MG	7654/21T	019879	REMEDICA LTD	C.z C.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Other variation
MUCOFALK ORANGE GRANULES FOR ORAL SUSPENSION 3.25G/5G SACHET	527/22T, 528/22T	007597	DR. FALK PHARMA GMBH	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or

				address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
MONTOL TABLET, CHEWABLE 4MG	1407/22T	021118	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
MONTOL TABLET, CHEWABLE 5MG	1408/22T	021119	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process

AIRTAL TABLET, FILM COATED 100MG	1302/22T	016332	ALMIRALL S.A.	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance- replacement or addition of a site where batch control/testing takes place
VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	1347/22T	012082	PFIZER HELLAS AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
PROCTO-GLYVENOL RECTAL CREAM	1206/22T	017441	RECORDATI HELLAS PHARMACEUTICALS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product

				Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
PROCTO-GLYVENOL SUPPOSITORY	1207/22T	018327	RECORDATI HELLAS PHARMACEUTICALS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SPIROLON TABLET, FILM COATED 25MG	1252/22T	007873	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SPIROLON TABLET, FILM COATED 100MG	1253/22T	008679	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TEGRETOL SYRUP 100MG/5ML	521/22T	018450	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
TEGRETOL CR MODIFIED-RELEASE TABLET 200MG	522/22T	018452	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF

				holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
TEGRETOL CR MODIFIED-RELEASE TABLET 400MG	523/22T	018451	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
TEGRETOL TABLET 200MG	520/22T	018437	NOVARTIS IRELAND LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture

				of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
LOSAR TABLET, FILM COATED 100MG	1068/22T	020787	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LOSAR TABLET, FILM COATED 50MG	1067/22T	020786	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LEVOMED TABLET 100MG/25MG	1060/22T	019837	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LEVOMED TABLET 250MG/25MG	1061/22T	019836	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
LEVOMED TABLET 100MG/10MG	1059/22T	019853	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MONTOL TABLET, FILM COATED 10MG	870/22T	021120	DELORBIS PHARMACEUTICALS LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	5461/21T	012082	PFIZER HELLAS AE	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes

SALOFALK ENEMA 4G/60ML	7326/21T, 7327/21T, 7328/21T	012246	DR. FALK PHARMA GMBH	B.II.e.7.a B.II.e.7.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Change in the name of a supplier of a packaging component. If the information is not needed in the dossier CMDh recommends deletion of this information. B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
PREPARATION H RECTAL OINTMENT (1+3)%	5912/21T	016005	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details)

				and/or changes in the Pharmacovigilance System Master File (PSMF) location
ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	2506/21T	016613	PIRAMAL CRITICAL CARE B.V.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
FOUCH VAGINAL CREAM 2%	1569/22T	019526	RAFARM S.A.	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
FOLIC ACID TABLET, FILM COATED 5MG	7591/21T, 7592/21T, 7593/21T, 7594/21T, 7595/21T, 7596/21T	008939	REMEDICA LTD	B.II.c.1.a B.II.c.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.z B.II.c.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Other variation B.II.c.1.b B.II.c.1.b -

				QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method
ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	2444/21T	016613	PIRAMAL CRITICAL CARE B.V.	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits
CANDIPLAS CREAM 2% W/W	1062/22T	019935	MEDOCHE MIE LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas
FLUDARA POWDER FOR SOLUTION FOR INJECTION/INFUSION 50MG	8/22T	018733	GENZYME EUROPE BV	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

SITALOM TABLET, FILM COATED 10MG	379/22T, 380/22T	021939	CODAL-SYNTO LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
SITALOM TABLET, FILM COATED 5MG	381/22T, 382/22T	021938	CODAL-SYNTO LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
SITALOM TABLET, FILM COATED 20MG	375/22T, 376/22T	021941	CODAL-SYNTO LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
SITALOM TABLET, FILM COATED 15MG	377/22T, 378/22T	021940	CODAL-SYNTO LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
ZYLAPOUR TABLET 300MG	9492/21T	016544	IASIS PHARMACEUTICALS HELLAS SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
MEDICINAL NITROUS OXIDE LINDE HADJIKYRIAKOS GAS LTD MEDICINAL GAS, LIQUEFIED 100%	1/22T, 2/22T, 3/22T, 4/22T	020297	LINDE HADJIKYRIAKOS GAS LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)

ZESTRIL TABLET 20MG	8782/21T	012876	ATNAHS PHARMA NETHERLANDS B.V.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ZESTRIL TABLET 10MG	8781/21T	012875	ATNAHS PHARMA NETHERLANDS B.V.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ZESTRIL TABLET 5MG	8780/21T	012874	ATNAHS PHARMA NETHERLANDS B.V.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	2446/21T, 2447/21T	016613	PIRAMAL CRITICAL CARE B.V.	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

				the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product* B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
FOLIC ACID TABLET, FILM COATED 5MG	9267/21T, 9268/21T	008939	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control

				takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
APONIL TABLET 100MG	1404/22T, 1405/22T	017417	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SYNTOCLAV TABLET, FILM COATED 875/125MG	6680/21T	021585	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
EXATRON TABLET, FILM COATED	307/22T	022347	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP

				changes (e.g. agreed wording + template change)
SYNTOCLAV TABLET, FILM COATED 375MG	6673/21T	017800	CODAL SYNTO LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
SYNTOCLAV TABLET, FILM COATED 625MG	6674/21T	017801	CODAL SYNTO LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
KLERIMED TABLET, FILM COATED 500MG	7189/21T, 7190/21T, 7191/21T	019195	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
KLERIMED TABLET, FILM COATED 250MG	7186/21T, 7187/21T, 7188/21T	019927	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate

				from an already approved manufacturer A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
XATRAL OD TABLET, PROLONGED-RELEASE 10MG	6774/21T	019244	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
XATRAL SUSTAINED RELEASE TABLETS 5MG	6773/21T	017139	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TAFLOTAN EYE DROPS, SOLUTION 15MCG/ML	3365/21T, 3366/21T	022835	VIANEX S.A	B.II.e.4.c B.II.e.4.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that affects the product information

ATORSTAN TABLET, FILM COATED 80MG	9055/21T, 9056/21T	020940	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATORSTAN TABLET, FILM COATED 40MG	9053/21T, 9054/21T	020939	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which

				no new additional data is required to be submitted by the MAH
ATORSTAN TABLET, FILM COATED 10MG	9049/21T, 9050/21T	020937	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATORSTAN TABLET, FILM COATED 20MG	9051/21T, 9052/21T	020938	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for

				the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PARIET TABLET, GASTRO-RESISTANT 20MG	720/22T, 721/22T, 722/22T, 723/22T	018888	JANSSEN-CILAG INTERNATIONAL NV	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer

				responsible for batch release, site where batch control takes place, or supplier of a starting
PARIET TABLET, GASTRO-RESISTANT 10MG	716/22T, 717/22T, 718/22T, 719/22T	018887	JANSSEN-CILAG INTERNATIONAL NV	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site

				where batch control takes place, or supplier of a starting
MEDOVIR CREAM 5% W/W	1197/22T, 1198/22T, 1199/22T, 1200/22T, 1201/22T, 1202/22T	020372	MEDOCHEMIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of

				Suitability covering the retest period is part of th
REMETHAN GEL 1% W/W	645/22T, 646/22T	014630	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
FOLIC ACID TABLET, FILM COATED 5MG	7532/21T, 7533/21T, 7534/21T	008939	REMEDICA LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
CELECOXIB ACCORD CAPSULE, HARD 200MG	380/21T	023492	ACCORD HEALTHCARE S.L.U	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

TAPTIQOM EYE DROPS, SOLUTION (15MCG/5MG)/ML	6857/21T, 6858/21T	023572	VIANEX S.A	B.II.e.4.c B.II.e.4.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that affects the product information
TAPTIQOM EYE DROPS, SOLUTION (15MCG/5MG)/ML	6877/21T	023572	VIANEX S.A	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
MELOX TABLET 15MG	651/22T	017763	MEDOCHE MIE LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
MELOX TABLET 7.5MG	650/22T	017762	MEDOCHE MIE LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
LANOXIN PG TABLET 0.0625MG	1193/22T	019787	ASPEN PHARMA TRADING LIMITED	B.II.d.1.i B.II.d.1.i - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Ph. Eur. 2.9.40 Uniformity of dosage units is introduced to replace the currently registered method, either Ph. Eur. 2.9.5 (Uniformity of mass). or Ph. Eur. 2.9.6 (Uniformity of content)
QUETRA ORAL SOLUTION 100MG/ML	1177/22T, 1178/22T, 1179/22T	021968	REMEDICA LTD	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT -

				Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
OLOXICAM TABLET 15MG	644/22T	021114	CODAL-SYNTO LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
GRANULOKINE SINGLEJECT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 30 MU (0,6 MG/ML)	6863/21T, 6864/21T	019765	AMGEN EUROPE B.V.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF B.I.a.1.k B.I.a.1.k - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - New storage site of Master Cell Bank and/or Working Cell Banks
GRANULOKINE SINGLEJECT SOLUTION FOR INJECTION IN PREFILLED SYRINGES 48 MU (0,96 MG/ML)	6865/21T, 6866/21T	019766	AMGEN EUROPE B.V.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF B.I.a.1.k B.I.a.1.k - QUALITY CHANGES - ACTIVE

				SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - New storage site of Master Cell Bank and/or Working Cell Banks
GRANULOKINE SOLUTION FOR INJECTION 0.3MG/ML VIAL	6861/21T, 6862/21T	019764	AMGEN EUROPE B.V.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF B.I.a.1.k B.I.a.1.k - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - New storage site of Master Cell Bank and/or Working Cell Banks
NAXAT TABLET, FILM COATED 10MG	308/22T	023499	DELORBIS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES -

				FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
NAXAT TABLET, FILM COATED 20MG	310/22T	023501	DELORBIS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
NAXAT TABLET, FILM COATED 15MG	309/22T	023500	DELORBIS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
VOLTAREN RETARD SUSTAINED RELEASE TABLETS 100MG	1167/22T	018444	NOVARTIS IRELAND LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle

				shield (different plastic used)) - Change that does not affect the product information
VOLTAREN SR SUSTAINED RELEASE TABLETS 75MG	1176/22T	018459	NOVARTIS IRELAND LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
PENOPEN TABLET, FILM COATED 800MG	132/22T, 133/22T, 134/22T	022762	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms
PENOPEN TABLET, FILM COATED 1G	135/22T, 136/22T, 137/22T	022763	REMEDICA LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or

				storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms
MEDOFLOXINE TABLET, FILM COATED 200MG	1190/22T	013357	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
NEXIUM I.V. POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG	8931/21T, 8932/21T, 8933/21T, 8934/21T, 8935/21T	019788	C G PAPALOISOU LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control

				testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on
SYNTOSARTIN PLUS TABLET, FILM COATED 150MG/12.5MG	1122/22T, 1123/22T	022199	CODAL-SYNTO LIMITED	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the

				finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
SYNTOSARTIN PLUS TABLET, FILM COATED 300MG/12.5MG	1124/22T, 1125/22T	022200	CODAL-SYNTO LIMITED	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and

				quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
SYNTOSARTIN PLUS TABLET, FILM COATED 300MG/25MG	1126/22T, 1127/22T	022201	CODAL-SYNTO LIMITED	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
ASPIRIN EXPRESS TABLET, COATED 500MG	3579/21T, 3580/21T, 3581/21T, 3582/21T	023554	BAYER HELLAS ABEE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
CLINIMIX N14G30E SOLUTION FOR INFUSION	4088/20T	018591	BAXTER (HELLAS) EPE	B.II.b.5 z) Change to inprocess test(s) or limits applied during the manufacture of the finished product Other variation
DIASPIL CAPSULE, HARD 5MG/10MG	9900/20T	023134	ANGELINI PHARMA HELLAS S.A	A.1 Change in the name and/or address of the marketing authorisation holder
DIASPIL CAPSULE, HARD 2.5MG/5MG	9903/20T	023131	ANGELINI PHARMA HELLAS S.A	A.1 Change in the name and/or address of the marketing authorisation holder
DIASPIL CAPSULE, HARD 5MG/5MG	9902/20T	023132	ANGELINI PHARMA HELLAS S.A	A.1 Change in the name and/or address of the marketing authorisation holder
DIASPIL CAPSULE, HARD 10MG/10MG	9899/20T	023135	ANGELINI PHARMA HELLAS S.A	A.1 Change in the name and/or address of the marketing authorisation holder
DIASPIL CAPSULE, HARD 10MG/5MG	9901/20T	023133	ANGELINI PHARMA HELLAS S.A	A.1 Change in the name and/or address of the marketing authorisation holder
ZOLOFT TABLET, FILM COATED 50MG	5653/21T	014677	UPJOHN HELLAS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ZOLOFT TABLET, FILM COATED 100MG	5654/21T	014678	UPJOHN HELLAS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SENSIBIO CREAM (20MG/1MG)/G	8930/21T	020908	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
FLUSTERIX CREAM 2% W/W	8972/21T	020903	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
BEZANIN TABLET, FILM COATED 500MG	925/22T, 926/22T, 927/22T	020894	IASIS PHARMACEUTICALS HELLAS SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SPECENIB TABLET, FILM COATED 70MG	863/22T	023047	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SPECENIB TABLET, FILM COATED 20MG	861/22T	023045	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product

				Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SPECENIB TABLET, FILM COATED 140MG	866/22T	023050	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SPECENIB TABLET, FILM COATED 100MG	865/22T	023049	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference

				product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SPECENIB TABLET, FILM COATED 80MG	864/22T	023048	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SPECENIB TABLET, FILM COATED 50MG	862/22T	023046	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
NORDITROPIN NORDIFLEX SOLUTION	8542/20T	022994	NOVO NORDISK A/S	C.I z) Changes (Safety/Efficacy) to Human and

FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML				Veterinary Medicinal Products Other variation
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	8541/20T	022995	NOVO NORDISK A/S	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	8543/20T	022993	NOVO NORDISK A/S	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
GLUCAGEN HYPOKIT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1MG	8540/20T	020205	NOVO NORDISK A/S	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 10MG/1.5ML	8548/20T	020803	NOVO NORDISK A/S	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	8546/20T	020990	NOVO NORDISK A/S	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	8544/20T	020992	NOVO NORDISK A/S	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	8545/20T	020991	NOVO NORDISK A/S	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 15MG/1.5ML	8547/20T	020804	NOVO NORDISK A/S	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 5MG/1.5ML	8549/20T	020802	NOVO NORDISK A/S	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	1253/21T	022994	NOVO NORDISK A/S	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	1252/21T	022995	NOVO NORDISK A/S	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	1251/21T	022993	NOVO NORDISK A/S	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 5MG/1.5ML	1246/21T	020802	NOVO NORDISK A/S	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 10MG/1.5ML	1247/21T	020803	NOVO NORDISK A/S	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	1250/21T	020992	NOVO NORDISK A/S	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	1254/21T	020991	NOVO NORDISK A/S	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	1249/21T	020990	NOVO NORDISK A/S	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 15MG/1.5ML	1248/21T	020804	NOVO NORDISK A/S	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
SINGULAIR GRANULES FOR ORAL SUSPENSION 4MG	2337/21T	019676	N.V. ORGANON	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
SINGULAIR TABLET, CHEWABLE 4MG	2338/21T	019291	N.V. ORGANON	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
EPSITRON TABLET 50MG	1191/22T	012097	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NAXAT TABLET, FILM COATED 10MG	1024/22T	023499	DELORBIS PHARMACEUTICALS LTD	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation

NAXAT TABLET, FILM COATED 20MG	1026/22T	023501	DELORBIS PHARMACEUTICALS LTD	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
NAXAT TABLET, FILM COATED 15MG	1025/22T	023500	DELORBIS PHARMACEUTICALS LTD	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	4660/20T, 4661/20T, 4662/20T	20630	CSL BEHRING GMBH	B.II.b.3 z) Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product Other variation B.II.d.2 a) Minor changes to an approved test procedure B.II.e.1 b) 3. Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form
ALBUREX 5 SOLUTION FOR INFUSION 50G/L	4663/20T, 4664/20T, 4665/20T	20629	CSL BEHRING GMBH	B.II.b.3 z) Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product Other variation B.II.d.2 a) Minor changes to an approved test procedure B.II.e.1 b) 3. Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form
OLANZAPINE AUROBINDO TABLET 10MG	3812/20T	022413	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1 a) 3. New certificate from a new manufacturer (replacement or addition)

OLANZAPINE AUROBINDO TABLET 5MG	3813/20T	022412	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1 a) 3. New certificate from a new manufacturer (replacement or addition)
ISOPTIN TABLET, FILM COATED 40MG	647/22T	006998	MYLAN IRE HEALTHCARE LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ISOPTIN SUSTAINED RELEASE TABLETS 240MG	649/22T	012250	MYLAN IRE HEALTHCARE LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ISOPTIN TABLET, FILM COATED 80MG	648/22T	006999	MYLAN IRE HEALTHCARE LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FERROVIN SOLUTION FOR INJECTION/CONCENTRATE	9737/21T	021660	RAFARM S.A.	C.I.11.a C.I.11.a - SAFETY, EFFICACY,

FOR SOLUTION FOR INFUSION 20MG/ML				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
EPSITRON TABLET 25MG	1192/22T	011128	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANTEX TABLET, FILM COATED 50MG	473/22T	021814	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the

				active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANTEX TABLET, FILM COATED 200MG	474/22T	021815	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MAALOX PLUS ORAL SUSPENSION	1048/22T	019265	SANOFI - AVENTIS CYPRUS LTD	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance

				System Master File (PSMF) location
BUSCOPAN TABLET, COATED 10MG	1052/22T	003125	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
MUCOSOLVAN SYRUP 30MG/5ML	1042/22T	021127	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
TELFAST TABLET, FILM COATED 180MG	1041/22T	018151	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of

				pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
BUSCOPAN PLUS TABLET, FILM COATED	1053/22T	014583	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
BATRAFEN MEDICATED NAIL LACQUER 8% W/W	1054/22T	016139	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance

				System Master File (PSMF) location
MUCOSOLVAN SYRUP 15MG/5ML	1044/22T	011682	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
MUCOSOLVAN SOLUTION FOR INJECTION 7.5MG/ML, 2ML VIALS	1043/22T	011681	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
DULCOLAX TABLET, GASTRO-RESISTANT 5MG	1049/22T	006121	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of

				pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
BUSCOPAN SOLUTION FOR INJECTION 20MG/ML	1051/22T	003121	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
MUCOSOLVAN PROLONGED RELEASE CAPSULES 75MG	1045/22T	019781	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance

				System Master File (PSMF) location
MAALOX PLUS TABLET, CHEWABLE	1047/22T	019267	SANOFI - AVENTIS CYPRUS LTD	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
MAALOX ORAL SUSPENSION (22.8+40)MG/ML	1046/22T	019266	SANOFI - AVENTIS CYPRUS LTD	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
DEXA-RHINASPRAY N NASAL SPRAY (0,02+0,12) MG/DOSE	1050/22T	019173	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of

				pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
HUMULIN REGULAR SOLUTION FOR INJECTION IN A CARTRIDGE 100IU/ML	5182/20T, 5183/20T, 5184/20T, 5185/20T	022893	PHADISCO LTD	B.II.b.5 b) Addition of a new test(s) and limits B.II.b.1 d) Site which requires an initial or product specific inspection
ZADITEN EYE DROPS, SOLUTION 0.25MG/ML	6453/20T	019261	LABORATO IRES THEA	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
AFEKSIN SOLUBLE TABLET 20MG	132/21T	023442	ACTAVIS GROUP PTC EHF	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
NEXIUM TABLET, GASTRO-RESISTANT 40MG	4366/21T	019421	C G PAPALOISO U LTD	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for

				medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
NEXIUM I.V. POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG	4364/21T	019788	C G PAPALOISO U LTD	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
ZOMIG TABLET, FILM COATED 2.5MG	4363/21T	017688	C G PAPALOISO U LTD	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location

NEXIUM TABLET, GASTRO-RESISTANT 20MG	4365/21T	019420	C G PAPALOISO U LTD	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
APO-GO PFS SOLUTION FOR INFUSION 5MG/ML IN PREFILLED SYRINGE	1650/21T, 1651/21T	021474	ITF HELLAS A.E.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01MG/ML	3163/21T, 3164/21T, 3165/21T, 3166/21T, 3167/21T, 3168/21T, 3169/21T, 3170/21T,	20566	INIBSA DENTAL S.L.U.	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED

	3171/21T, 3172/21T, 3173/21T, 3174/21T			PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specificatio B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved sp
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005MG/ML	3175/21T, 3176/21T, 3177/21T, 3178/21T, 3179/21T, 3180/21T, 3181/21T, 3182/21T, 3183/21T, 3184/21T, 3185/21T, 3186/21T	20565	INIBSA DENTAL S.L.U.	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification

				parameters and/or limits of the finished product - Deletion of a non-significant B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specificatio B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved sp
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01MG/ML	3024/21T, 3025/21T, 3026/21T, 3027/21T	20566	INIBSA DENTAL S.L.U.	B.II.a.3.b.2 B.II.a.3.b.2 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients -

				Qualitative or quantitative changes in one or more excipients that may B.II.b.3.e B.II.b.3.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Introduction or increase in the overag B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overa B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005MG/ML	3028/21T, 3029/21T, 3030/21T, 3031/21T	20565	INIBSA DENTAL S.L.U.	B.II.a.3.b.2 B.II.a.3.b.2 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients -

				Qualitative or quantitative changes in one or more excipients that may B.II.b.3.e B.II.b.3.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Introduction or increase in the overag B.II.b.5.e B.II.b.5.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overa B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01MG/ML	3048/21T	20566	INIBSA DENTAL S.L.U.	B.II.e.4.b B.II.e.4.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - The

				change in shape or dimensions concerns a fundamental part of the packaging material, which may have a significant impact on the delivery, use, safety or stability of the finished product
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005MG/ML	3049/21T	20565	INIBSA DENTAL S.L.U.	B.II.e.4.b B.II.e.4.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - The change in shape or dimensions concerns a fundamental part of the packaging material, which may have a significant impact on the delivery, use, safety or stability of the finished product
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01MG/ML	3032/21T, 3033/21T, 3034/21T, 3035/21T, 3036/21T, 3037/21T, 3038/21T, 3039/21T	20566	INIBSA DENTAL S.L.U.	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.d B.II.e.2.d - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition or replacement of a specification parameter as a result of a safety or quality issue
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005MG/ML	3040/21T, 3041/21T, 3042/21T, 3043/21T, 3044/21T, 3045/21T, 3046/21T, 3047/21T	20565	INIBSA DENTAL S.L.U.	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.d B.II.e.2.d - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition or replacement of a specification parameter as a result of a safety or quality issue
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005MG/ML	3767/21T	20565	INIBSA DENTAL S.L.U.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change

				in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01MG/ML	3768/21T	20566	INIBSA DENTAL S.L.U.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
ZOTRON SOLUTION FOR INJECTION 2MG/ML	1022/22T, 1023/22T	020384	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product

				Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
PRIMPERAN SOLUTION FOR INJECTION 10MG/2ML	6534/21T	016090	SANOFI-AVENTIS GROUPE	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PRIMPERAN TABLET 10MG	6535/21T	016093	SANOFI-AVENTIS GROUPE	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	5518/21T	022321	CSL BEHRING GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	5520/21T	023121	CSL BEHRING GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	5519/21T	023120	CSL BEHRING GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	5517/21T	020564	CSL BEHRING GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
GROWFIN TABLET, FILM COATED 1MG	7287/21T	021614	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TAVANIC PARENTERAL SOLUTION FOR INFUSION 500MG/100ML	10298/20T, 10299/20T	019282	SANOFI - AVENTIS CYPRUS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal

				products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
TAVANIC TABLET, FILM COATED 500MG	10300/20T, 10301/20T	019283	SANOFI - AVENTIS CYPRUS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the

				assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
TAVANIC PARENTERAL SOLUTION FOR INFUSION 500MG/100ML	6875/21T	019282	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TAVANIC TABLET, FILM COATED 500MG	6876/21T	019283	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ILGEM SHAMPOO 20MG/G	9031/21T	016852	COSTAKIS TSISIOS & CO LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EUTHYROX TABLET 100MCG	3517/21T	019426	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
EUTHYROX TABLET 50MCG	3516/21T	019425	MERCK A E HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data

CEFIZOL POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	916/22T	021454	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CEFIZOL POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG	915/22T	021453	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRILEPTAL TABLET, FILM COATED 150MG	761/22T	019109	NOVARTIS IRELAND LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
HEMOSOL B0 SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS	8492/21T	023511	GAMBRO LUNDIA AB	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DEXAMETHASONE PHOSPHATE NORIDEM SOLUTION FOR INJECTION 4MG/ML	4783/21T	023415	NORIDEM ENTERPRISES LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BIPHOZYL SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 22MMOL/L	4121/21T	022333	BAXTER HOLDING B.V.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
SADERON TABLET, FILM COATED 2.5MG	770/22T	022803	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FASTUM GEL 2.5%	827/22T	013370	A. MENARINI INDUSTRIE FARMACEUT	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

			ICHE RIUNITE SRL	CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRACRIUM INJECTION 10MG/ML	670/22T	010430	ASPEN PHARMA TRADING LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
AZEPTIL CAPSULE, HARD 500MG	9518/21T	013426	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AZEPTIL CAPSULE, HARD 250MG	9517/21T	013414	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AXETINE TABLET, FILM COATED 500MG	635/22T, 636/22T, 637/22T	020763	MEDOCHE MIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AXETINE TABLET, FILM COATED 250MG	632/22T, 633/22T, 634/22T	020762	MEDOCHEMIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate

				from an already approved manufacturer
ZOTRON TABLET, FILM COATED 8MG	1020/22T, 1021/22T	020386	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ZOTRON TABLET, FILM COATED 4MG	1018/22T, 1019/22T	020385	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
CEFUROXIME-SYNTO TABLET, FILM COATED 500MG	482/22T, 483/22T, 484/22T	021582	CODAL-SYNTO LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site

				where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CEFUROXIME-SYNTO TABLET, FILM COATED 250MG	479/22T, 480/22T, 481/22T	021581	CODAL-SYNTO LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of

				suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	4250/21T, 4251/21T, 4252/21T	019724	MERCK SHARP & DOHME BV	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Updated certificate from an already approved manufacturer
VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	4587/21T	019724	MERCK SHARP & DOHME BV	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an excipient or reagent with TSE risk - Other variation
NIMBEX SOLUTION FOR INJECTION OR INFUSION 2MG/ML	669/22T	018088	ASPEN PHARMA TRADING LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the

				name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
TEVETEN PLUS TABLET, FILM COATED 600MG/12.5MG	6591/21T, 6592/21T	020235	MYLAN HEALTHCARE GMBH, HANNOVER	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
TEVETEN PLUS TABLET, FILM COATED 600MG/12.5MG	6146/21T	020235	MYLAN HEALTHCARE GMBH, HANNOVER	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Reduction in the testing frequency of an analysis, from routine testing to skip or periodic testing (microbial testing of finished product).
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	117/22T	019523	SANOFI PASTEUR.	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply

				with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	867/22T	021944	MEDOCHEMIE LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	868/22T	019896	MEDOCHEMIE LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	869/22T	019897	MEDOCHEMIE LTD	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	7151/20T	022522	ACCORD HEALTHCARE S.L.U	C.I.3 z) Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 Other variation

MAVIXAN TABLET 5MG	1575/20T, 1576/20T	021313	PHARMATHEN S.A.	C.I.8 a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2 b) for Nationally Authorised Products
MAVIXAN TABLET 10MG	1573/20T, 1574/20T	021314	PHARMATHEN S.A.	C.I.8 a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location A.2 b) for Nationally Authorised Products
LAVIFENT PATCH, TRANSDERMAL 50MCG/HOUR	5714/21T	020840	PHARMABIDE LTD, HALANDRI	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LAVIFENT PATCH, TRANSDERMAL 100MCG/HOUR	5712/21T	020842	PHARMABIDE LTD, HALANDRI	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LAVIFENT PATCH, TRANSDERMAL 75MGG/HOUR	5713/21T	020841	PHARMABIDE LTD, HALANDRI	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LAVIFENT PATCH, TRANSDERMAL 25MCG/HOUR	5715/21T	020839	PHARMABIDE LTD, HALANDRI	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LOTEMAX EYE DROPS 0.5%	8456/21T	020230	DR.GERHARD MANN CHEM.-PHARM. FABRIK GMBH	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing

REGAINE MEN'S FOAM CUTANEOUS FOAM 5% W/W	8641/21T	022275	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
REGAINE CUTANEOUS SOLUTION 5% W/V	8639/21T	019985	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
REGAINE CUTANEOUS SOLUTION 2% W/V	8640/21T	019984	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
YENLIP PESSARY 100MG	8808/21T	023439	VERISFIELD SINGLE MEMBER S.A.	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
DUSPATALIN TABLET, COATED 135MG	6352/21T	009670	MYLAN IRE HEALTHCARE LIMITED	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
DUSPATALIN RETARD CAPSULE, HARD, PROLONGED-RELEASE 200MG	6353/21T	016991	MYLAN IRE HEALTHCARE LIMITED	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
REGIOCIT SOLUTION FOR HAEMOFILTRATION	5287/21T	022304	GAMBRO LUNDIA AB	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
HEXAFLU DAY & NIGHT TABLET 500MG/60MG AND 500MG/25MG	1516/21T	023165	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet

				due to new quality, preclinical, clinical or pharmacovigilance data
AVERNOL TABLET 25MG	665/22T	020151	MEDOCHEMIE LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
COALIMAX TABLET 40/12.5MG	487/22T	021923	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
COALIMAX TABLET 80/12.5MG	488/22T	021924	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
COALIMAX TABLET 80/25MG	489/22T	021925	DELORBIS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of

				manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AMBEN CAPSULE, HARD 500MG	9520/21T	019852	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZYLORIC TABLET 300MG	9523/21T	019525	ASPEN PHARMA TRADING LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGIL ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR

				or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZYLORIC TABLET 100MG	9522/21T	019524	ASPEN PHARMA TRADING LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MILDRONATE CAPSULE, HARD 500MG	9102/21T	023526	PHARMEX ON CONSULTIN G S.R.O.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TEGRETOL SYRUP 100MG/5ML	9396/21T	018450	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not

				including batch control/testing
DEPAKINE CHRONO TABLET, PROLONGED-RELEASE 500MG	656/22T	019172	SANOFI-AVENTIS GROUPE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMIODARONE TABLET 200MG	9035/21T	019892	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

EMFORAL TABLET, FILM COATED 40MG	658/22T	019730	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EMFORAL TABLET, FILM COATED 10MG	659/22T	019733	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MEDSAMIC SOLUTION FOR INJECTION 100MG/ML	8913/20T, 8914/20T	021959	MEDOCHEMIE LTD	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes
MEDSAMIC SOLUTION FOR INJECTION 100MG/ML	76/21T	021959	MEDOCHE MIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DEXA-SYNTO ELIXIR ORAL SOLUTION 0.5MG/5ML	655/22T	022055	CODAL-SYNTO LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DEXAMED SOLUTION FOR INJECTION OR INFUSION 4MG/ML	652/22T, 653/22T	013416	MEDOCHE MIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
QUELORAN TABLET, PROLONGED-RELEASE 300MG	3566/20T	023410	PHARMATHEN S.A.	B.III.1 a) 2. Updated certificate from an already approved manufacturer
QUELORAN TABLET, PROLONGED-RELEASE 150MG	3568/20T	023408	PHARMATHEN S.A.	B.III.1 a) 2. Updated certificate from an already approved manufacturer
QUELORAN TABLET, PROLONGED-RELEASE 400MG	3565/20T	023411	PHARMATHEN S.A.	B.III.1 a) 2. Updated certificate from an already approved manufacturer
QUELORAN TABLET, PROLONGED-RELEASE 50MG	3564/20T	023407	PHARMATHEN S.A.	B.III.1 a) 2. Updated certificate from an already approved manufacturer
QUELORAN TABLET, PROLONGED-RELEASE 200MG	3567/20T	023409	PHARMATHEN S.A.	B.III.1 a) 2. Updated certificate from an already approved manufacturer
QUELORAN TABLET, PROLONGED-RELEASE 300MG	6228/20T	023410	PHARMATHEN S.A.	C.I.2 a) Implementation of change(s) for which no new additional data is required to

				be submitted by the MAH
QUELORAN TABLET, PROLONGED-RELEASE 150MG	6230/20T	023408	PHARMATHEN S.A.	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
QUELORAN TABLET, PROLONGED-RELEASE 400MG	6227/20T	023411	PHARMATHEN S.A.	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
QUELORAN TABLET, PROLONGED-RELEASE 50MG	6231/20T	023407	PHARMATHEN S.A.	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
QUELORAN TABLET, PROLONGED-RELEASE 200MG	6229/20T	023409	PHARMATHEN S.A.	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
QUELORAN TABLET, PROLONGED-RELEASE 300MG	4061/20T	023410	PHARMATHEN S.A.	A.2 b) for Nationally Authorised Products
QUELORAN TABLET, PROLONGED-RELEASE 150MG	4063/20T	023408	PHARMATHEN S.A.	A.2 b) for Nationally Authorised Products
QUELORAN TABLET, PROLONGED-RELEASE 400MG	4064/20T	023411	PHARMATHEN S.A.	A.2 b) for Nationally Authorised Products
QUELORAN TABLET, PROLONGED-RELEASE 50MG	4065/20T	023407	PHARMATHEN S.A.	A.2 b) for Nationally Authorised Products
QUELORAN TABLET, PROLONGED-RELEASE 200MG	4062/20T	023409	PHARMATHEN S.A.	A.2 b) for Nationally Authorised Products
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+100)MCG/DOSE	122/22T	021399	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing

				process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+500)MCG/DOSE	124/22T	020862	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+250)MCG/DOSE	123/22T	020861	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BRUFEN TABLET, COATED 400MG	8578/21T	005754	MYLAN IRE HEALTHCARE LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
AMIROL TABLET, FILM COATED 25MG	9312/21T	007748	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMIROL TABLET, FILM COATED 10MG	9313/21T	007749	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SEROQUEL TABLET, FILM COATED 200MG	4562/21T	017718	ASTRAZENECA AB	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SEROQUEL TABLET, FILM COATED 100MG	4560/21T	017717	ASTRAZENECA AB	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SEROQUEL TABLET, FILM COATED 25MG	4561/21T	017716	ASTRAZENECA AB	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SEROQUEL XR TABLET, PROLONGED-RELEASE 150MG	4557/21T	020699	ASTRAZENECA AB	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product

				Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SEROQUEL XR TABLET, PROLONGED-RELEASE 400MG	4556/21T	020359	ASTRAZENECA AB	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SEROQUEL XR TABLET, PROLONGED-RELEASE 300MG	4558/21T	020358	ASTRAZENECA AB	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SEROQUEL XR TABLET, PROLONGED-RELEASE 200MG	4555/21T	020357	ASTRAZENECA AB	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SEROQUEL XR TABLET, PROLONGED-RELEASE 50MG	4559/21T	020356	ASTRAZENECA AB	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal

				products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
APILONE TABLET, CHEWABLE 4MG	7820/20T	020821	PHARMATHEN S.A.	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
APILONE TABLET, CHEWABLE 5MG	7819/20T	020822	PHARMATHEN S.A.	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	5904/21T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
VILLAMOS OD TABLET, ORODISPERSIBLE 10MG	108/22T, 109/22T, 110/22T	021557	ELPEN PHARMACEUTICAL CO INC	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including

				replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
VILLAMOS OD TABLET, ORODISPERSIBLE 15MG	111/22T, 112/22T, 113/22T	021558	ELPEN PHARMACEUTICAL CO INC	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its

				corresponding test method B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
VILLAMOS OD TABLET, ORODISPERSIBLE 5MG	105/22T, 106/22T, 107/22T	021556	ELPEN PHARMACEUTICAL CO INC	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
VILLAMOS OD TABLET, ORODISPERSIBLE 20MG	114/22T, 115/22T, 116/22T	021559	ELPEN PHARMACEUTICAL CO INC	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and

				composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
TRANEXAMIC ACID TABLET, FILM COATED 500MG	435/22T	019921	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate

				from an already approved manufacturer
VENTOLIN EVOHALER AEROSOL 100MCG/DOSE	82/22T	018619	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
FLIVEN TABLET, FILM COATED 50MG	541/22T	021531	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLIVEN TABLET, FILM COATED 25MG	540/22T	021530	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MENTIFAR TABLET, FILM COATED 10MG	6763/21T	022204	RAFARM S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
MENTIFAR TABLET, FILM COATED 20MG	6764/21T	022205	RAFARM S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
LESCOL XL TABLET, PROLONGED-RELEASE 80MG	2781/20T	019110	NOVARTIS IRELAND LIMITED	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
CLOPIDOGREL ACCORD TABLET, FILM COATED 75MG	7179/21T	021757	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
METHOTREXATE TABLET, FILM COATED 2.5MG	550/22T	009132	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LOPERIUM CAPSULE, HARD 2MG	9515/21T, 9516/21T	008682	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a

				former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
LOPERIUM TABLET 2MG	9512/21T, 9513/21T, 9514/21T	019736	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
ROSUVASTATIN ACINO TABLET, FILM COATED 20MG	9458/21T	022940	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROSUVASTATIN ACINO TABLET, FILM COATED 5MG	9456/21T	022938	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROSUVASTATIN ACINO TABLET, FILM COATED 10MG	9457/21T	022939	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosi

				milar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROSUVASTATIN ACINO TABLET, FILM COATED 40MG	9459/21T	022941	ACINO AG	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BUSCOFEM CAPSULE, SOFT 400MG	3561/21T	022424	SANOFI AVENTIS AEBE	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BEGALIN-P POWDER FOR SOLUTION FOR INJECTION (1G/2G)/VIAL	8365/21T	013278	PFIZER HELLAS AE	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
MEDOVIR TABLET 800MG	621/22T, 622/22T	014928	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MEDOVIR TABLET 200MG	617/22T, 618/22T	012781	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MEDOVIR TABLET 400MG	619/22T, 620/22T	014927	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LYBEREN TABLET, FILM COATED 500MG	69/22T	021962	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LYBEREN TABLET, FILM COATED 250MG	68/22T	021961	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LYBEREN TABLET, FILM COATED 1000MG	70/22T	021964	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CINNARON TABLET 25MG	432/22T, 433/22T	008557	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial

				Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
CINNARON CAPSULE, HARD 75MG	430/22T, 431/22T	011726	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test

				period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
TREVUSIN CAPSULE, HARD 8MG	7112/21T, 7113/21T, 7114/21T, 7115/21T	023388	DELORBIS PHARMACEUTICALS LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where r B.I.b.2.c B.I.b.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance -

				Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the
TREVUSIN CAPSULE, HARD 4MG	7116/21T, 7117/21T, 7118/21T, 7119/21T	023387	DELORBIS PHARMACEUTICALS LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where r B.I.b.2.c B.I.b.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or

				limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the
CONVERIUM TABLET 75MG	8203/21T	020764	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIUM TABLET 150MG	8204/21T	020765	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
CONVERIUM TABLET 300MG	8205/21T	020766	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIUM TABLET 75MG	8197/21T, 8198/21T	020764	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIUM TABLET 150MG	8199/21T, 8200/21T	020765	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES -

				CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CONVERIUM TABLET 300MG	8201/21T, 8202/21T	020766	MEDOCHEMIE LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CLOZAREM TABLET 25MG	7263/21T	020348	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the

				Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
CLOZAREM TABLET 100MG	7264/21T	019378	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VILLAMOS TABLET, FILM COATED 5MG	99/22T, 100/22T, 101/22T	021552	ELPEN PHARMACEUTICAL CO INC	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished

				product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
VILLAMOS TABLET, FILM COATED 10MG	102/22T, 103/22T, 104/22T	021553	ELPEN PHARMACEUTICAL CO INC	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished

				product - Change in test procedure for the finished product - Minor changes to an approved test procedure
VILLAMOS TABLET, FILM COATED 2.5MG	96/22T, 97/22T, 98/22T	021551	ELPEN PHARMACEUTICAL CO INC	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
DAKTACORT 2%/1% W/W CREAM	8971/21T	007082	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet

				due to new quality, preclinical, clinical or pharmacovigilance data
REMABIRAT TABLET, FILM COATED 500MG	7148/21T	023458	REMEDICA LTD	C.I.6.b C.I.6.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication
REMABIRAT TABLET, FILM COATED 250MG	7147/21T	023457	REMEDICA LTD	C.I.6.b C.I.6.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication
TRIOFAN FOR ADULTS NASAL DROPS (1+10)MG	8048/21T	019346	THE STAR MEDICINES IMPORTERS CO. LTD	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
TRIOFAN FOR CHILDREN NASAL DROPS (0.5+5)MG	8049/21T	019345	THE STAR MEDICINES IMPORTERS CO. LTD	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range

FRUMIL TABLET	7321/21T	019400	SANOFI-AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CENCIPRAL TABLET, FILM COATED 60MG	130/22T	023194	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
CENCIPRAL TABLET, FILM COATED 30MG	129/22T	023193	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
CENCIPRAL TABLET, FILM COATED 90MG	131/22T	023195	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)

BETAC TABLET, FILM COATED 20MG	1336/21T, 1337/21T, 1338/21T	017976	MEDOCHE MIE LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
VIOPLEX-T POWDER, CUTANEOUS SPRAY	77/22T	020519	MEDICAIR BIOSCIENCE LABORATOR	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES -

			IES CY LIMITED	FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
FEMARA TABLET, FILM COATED 2.5MG	6217/20T	018468	NOVARTIS IRELAND LIMITED	C.I.11 z) Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan Other variation
STATOL TABLET, FILM COATED 40MG	311/22T	022937	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
STATOL TABLET, FILM COATED 20MG	312/22T	022936	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
STATOL TABLET, FILM COATED 10MG	313/22T	022935	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
STATOL TABLET, FILM COATED 5MG	314/22T	022934	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient -

				European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANESTEN VAGINAL TABLET 500MG	5/22T, 6/22T, 7/22T	023091	BAYER HELLAS ABEE	B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes B.II.e.1.z B.II.e.1.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Other changes B.II.f.1.z B.II.f.1.z - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Other variation
AVAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 160 ANTIGEN UNITS/0.5ML	1061/21T	017602	SANOFI PASTEUR.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
OXYCONTIN TABLET, PROLONGED-RELEASE 40MG	5310/21T	018610	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OXYCONTIN TABLET, PROLONGED-RELEASE 10MG	5308/21T	018608	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OXYCONTIN TABLET, PROLONGED-RELEASE 80MG	5311/21T	018611	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OXYCONTIN TABLET, PROLONGED-RELEASE 20MG	5309/21T	018609	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality,

				preclinical, clinical or pharmacovigilance data
OXYCONTIN TABLET, PROLONGED-RELEASE 5MG	5307/21T	020346	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FOSRENOL TABLET, CHEWABLE 1000MG	10643/20T	020048	SHIRE PHARMACEUTICALS IRELAND LIMITED.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FOSRENOL TABLET, CHEWABLE 750MG	10645/20T	020047	SHIRE PHARMACEUTICALS IRELAND LIMITED.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 C.I.4 - SAFETY,

				EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FOSRENOL TABLET, CHEWABLE 500MG	10646/20T	020046	SHIRE PHARMACEUTICALS IRELAND LIMITED.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FOSRENOL TABLET, CHEWABLE 250MG	10647/20T	020045	SHIRE PHARMACEUTICALS IRELAND LIMITED.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FOSRENOL ORAL POWDER 1000MG	10642/20T	021929	SHIRE PHARMACEUTICALS IRELAND LIMITED.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FOSRENOL ORAL POWDER 750MG	10644/20T	021928	SHIRE PHARMACEUTICALS IRELAND LIMITED.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ENGERIX-B PEDIATRIC SUSPENSION FOR INJECTION 10MCG/0.5ML	4304/21T	012940	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ENGERIX-B SUSPENSION FOR INJECTION 20MCG/1ML	4305/21T	012941	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
TRIATEC PLUS TABLET 5MG/25MG	7064/21T	019071	SANOFI-AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
COSTI TABLET 10MG	9408/21T	009119	MEDOCHEMIE LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
TRIATEC TABLET 2.5MG	7065/21T	012904	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TRIATEC TABLET 5MG	7066/21T	012905	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation

FLIXOTIDE DISKUS POWDER FOR INHALATION 250MCG	3209/21T	019606	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
FLIXOTIDE DISKUS POWDER FOR INHALATION 100MCG	3208/21T	019556	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
SERETIDE EVOHALER PRESSURISED INHALATION, SUSPENSION 25MCG/50MCG	3207/21T	019553	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
DEXAMETHASONE/RAFARM [PF] EYE DROPS, SOLUTION 1MG/ML	3942/21T, 3943/21T	023006	RAFARM S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product
DEXAMETHASONE/RAFARM [PF] EYE DROPS, SOLUTION 1MG/ML	7068/21T, 7069/21T	023006	RAFARM S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of

				human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
DEXAMED TABLET 1.5MG	9748/21T	019973	MEDOCHE MIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DEXAMED TABLET 0.5MG	9747/21T	019974	MEDOCHE MIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 750MG	2140/21T, 2141/21T, 2142/21T, 2143/21T, 2144/21T, 2145/21T, 2146/21T, 2147/21T	022948	MERCK A E HELLAS	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished produc B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and l B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finishe
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 1000MG	2132/21T, 2133/21T, 2134/21T, 2135/21T, 2136/21T, 2137/21T, 2138/21T, 2139/21T	022949	MERCK A E HELLAS	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished produc B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT -

				Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and l B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finishe
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 500MG	2148/21T, 2149/21T, 2150/21T, 2151/21T, 2152/21T, 2153/21T, 2154/21T, 2155/21T	022947	MERCK A E HELLAS	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished produc B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and l B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finishe
CORYCARDON TABLET, FILM COATED 300/25MG	9488/21T	020761	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

CORYCARDON TABLET, FILM COATED 300/12.5MG	9487/21T	020760	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CORYCARDON TABLET, FILM COATED 150/12.5MG	9486/21T	020759	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZESTORETIC TABLET	8770/21T	013839	ATNAHS PHARMA	A.7 A.7 - ADMINISTRATIVE

			NETHERLANDS B.V.	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NEOSTIGMIN SOLUTION FOR INJECTION 2.5MG/1ML	7666/21T	012403	COOPER SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LAMOSYNT TABLET 200MG	7551/21T	021490	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMOSYNT TABLET 25MG	7548/21T	021487	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of

				suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMOSYNT TABLET 50MG	7549/21T	021488	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMOSYNT TABLET 100MG	7550/21T	021489	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
GEMCITABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	7412/20T	021481	ACCORD HEALTHCARE S.L.U	C.I.11 z) Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan Other variation
FLIXOTIDE EVOHALER 125MCG	9731/21T, 9732/21T	016809	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.e.7.z B.II.e.7.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Other changes B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
AUGMENTIN ES POWDER FOR ORAL SUSPENSION (600+42.9)MG/5ML	859/21T, 860/21T	020148	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PROGRAF CAPSULE, HARD 0.5MG	5648/20T	022365	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PROGRAF CAPSULE, HARD 1MG	5647/20T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	5645/20T	019080	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.

PROGRAF CAPSULE, HARD 5MG	5646/20T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	7637/21T	019161	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	7635/21T	019160	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	7634/21T	019159	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	7636/21T	019744	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MEROPENEM VENUS POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	156/21T	021662	VENUS PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MEROPENEM VENUS POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/VIAL	155/21T	021663	VENUS PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BETACORT CREAM	76/22T	020146	MEDICAIR BIOSCIENCE LABORATORIES CY LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
CASODEX TABLET, FILM COATED 50MG	10/22T, 11/22T, 12/22T, 13/22T, 14/22T, 15/22T	018331	LABORATOIRES JUVISE PHARMACEUTICALS	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-

				significant specification parameter (e B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specifi
SYNTOVIR TABLET 800MG	5330/21T, 6543/21T	018641	CODAL-SYNTO LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SYNTOVIR TABLET 400MG	5329/21T, 6542/21T	018352	CODAL-SYNTO LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - Eur A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SYNTOVIR TABLET 200MG	5328/21T, 6541/21T	018353	CODAL-SYNTO LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient -

				Eur A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NUROFEN FOR CHILDREN 4% ORANGE ORAL SUSPENSION 4%	5490/20T, 5491/20T	021712	RECKITT BENCKISER HELLAS HEALTHCAR E SA	B.III.1 a) 2. Updated certificate from an already approved manufacturer
NUROFEN FOR CHILDREN 4% STRAWBERRY ORAL SUSPENSION 4%	5488/20T, 5489/20T	021713	RECKITT BENCKISER HELLAS HEALTHCAR E SA	B.III.1 a) 2. Updated certificate from an already approved manufacturer
STORILAT R TABLET, PROLONGED-RELEASE 400MG	9641/21T	014793	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
STORILAT TABLET 200MG	9642/21T	008549	REMEDICA LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
SOLPADEINE MAX SOLUBLE EFFERVESCENT TABLET 500MG/30MG/12.8MG	1228/21T	022825	OMEGA PHARMA HELLAS S.A	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
IRBESARTAN ACCORD TABLET, FILM COATED 150MG	7403/21T	021645	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

SERETIDE EVOHALER PRESSURISED INHALATION, SUSPENSION 25MCG/50MCG	3364/21T	019553	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LETROZOLE TEVA TABLET, FILM COATED 2.5MG	4953/21T, 4954/21T	021073	TEVA PHARMA BV	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
LEVOXACIN TABLET, FILM COATED 500MG	10259/20T	020748	SAPIENS PHARMACEUTICALS LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
LEVOXACIN TABLET, FILM COATED 250MG	10260/20T	020747	SAPIENS PHARMACEUTICALS LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
LUCIDEL TABLET, FILM COATED 75MG	8779/21T	021869	ELPEN PHARMACEUTICAL CO INC	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

				the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
LUCIDEL TABLET, FILM COATED 150MG	8778/21T	021870	ELPEN PHARMACEUTICAL CO INC	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
LUCIDEL TABLET, FILM COATED 300MG	8777/21T	021871	ELPEN PHARMACEUTICAL CO INC	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ADVECIT CAPSULE, HARD 5MG	9409/21T	021445	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ADVECIT CAPSULE, HARD 20MG	9410/21T	021446	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ADVECIT CAPSULE, HARD 140MG	9412/21T	021448	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosi

				milar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ADVECIT CAPSULE, HARD 250MG	9414/21T	021450	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ADVECIT CAPSULE, HARD 180MG	9413/21T	021449	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to

				be submitted by the MAH
ADVECIT CAPSULE, HARD 100MG	9411/21T	021447	DELORBIS PHARMACEUTICALS LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
AMARYL TABLET 1MG	7485/21T	020550	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AMARYL TABLET 4MG	7488/21T	20553	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AMARYL TABLET 3MG	7487/21T	20552	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AMARYL TABLET 2MG	7486/21T	20551	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ROSU-ASA CAPSULE, HARD 5MG/100MG	3243/21T	023199	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data

ROSU-ASA CAPSULE, HARD 10MG/100MG	3244/21T	023200	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ROSU-ASA CAPSULE, HARD 20MG/100MG	3245/21T	023201	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GRAFALON CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	3624/21T	017186	NEOVII BIOTECH GMBH	B.II.b.z B.II.b.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Other variation
NOOTROPIL ORAL SOLUTION 200MG/ML	6487/21T, 6488/21T	007087	UCB PHARMA SA	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result

				of a safety or quality issue B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ACCUPRON TABLET, FILM COATED 20MG	9616/21T	013096	PFIZER HELLAS AE	B.II.a.1.b B.II.a.1.b - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in scoring/break lines intended to divide into equal doses
ACCUPRON TABLET, FILM COATED 5MG	9615/21T	013095	PFIZER HELLAS AE	B.II.a.1.b B.II.a.1.b - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in scoring/break lines intended to divide into equal doses
FERROVIN SOLUTION FOR INJECTION/CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	9639/21T, 9640/21T	021660	RAFARM S.A.	C.I.12 C.I.12 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Inclusion or deletion of black symbol and

				explanatory statements for medicinal products in the list of medicinal products that are subject to additional monitoring C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
INEGY TABLET 10MG/10MG	2333/21T	020129	MERCK SHARP & DOHME BV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
INEGY TABLET 10MG/40MG	2335/21T	020131	MERCK SHARP & DOHME BV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
INEGY TABLET 10MG/80MG	2336/21T	020132	MERCK SHARP & DOHME BV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
INEGY TABLET 10MG/20MG	2334/21T	020130	MERCK SHARP & DOHME BV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ACT-HIB POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 10MCG/0.5ML	4448/21T	014308	SANOFI PASTEUR.	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active

				substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	4449/21T	019523	SANOFI PASTEUR.	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes
COSTI TABLET 10MG	9407/21T	009119	MEDOCHE MIE LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	4188/21T, 4189/21T	022950	APTA MEDICA INTERNACIO NAL D.O.O.	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED

				PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/VIAL	4190/21T, 4191/21T	022951	APTA MEDICA INTERNACIONAL D.O.O.	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
EXEDRAL 25 TABLET, FILM COATED 25MG	714/21T, 715/21T	022057	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
FUCITHALMIC EYE DROPS, SUSPENSION 1%	2734/21T	010277	AMDIPHARM LIMITED	B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products
EXEDRAL 25 TABLET, FILM COATED 25MG	720/21T, 721/21T, 722/21T	022057	REMEDICA LTD	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance

				For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
CALCIUM-SANDOZ FORTE EFFERVESCENT TABLET 500MG	5804/21T	018988	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
IRBESARTAN VOCATE TABLET 300MG	6204/21T	022093	VOCATE PHARMACEUTICALS SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
IRBESARTAN VOCATE TABLET 150MG	6203/21T	022092	VOCATE PHARMACEUTICALS SA	C.I.11.a C.I.11.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of wording agreed by the competent authority
ZYRTEC ORAL SOLUTION 0.1%	4754/21T	016365	UCB PHARMA SA	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
ZYRTEC TABLET, FILM COATED 10MG	4753/21T	013066	UCB PHARMA SA	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active

				substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
ZYRTEC ORAL SOLUTION 0.1%	3107/21T	016365	UCB PHARMA SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZYRTEC TABLET, FILM COATED 10MG	3106/21T	013066	UCB PHARMA SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VALGANCICLOVIR AUROBINDO TABLET, FILM COATED 450MG	3489/21T	022358	AUROBINDO PHARMA (MALTA) LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	6458/21T, 6459/21T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites

				for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
KANILAD TABLET, FILM COATED 200MG	7277/21T	022716	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
KANILAD TABLET, FILM COATED 50MG	7274/21T	022713	MEDOCHEMIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of

				change(s) for which no new additional data is required to be submitted by the MAH
KANILAD TABLET, FILM COATED 150MG	7276/21T	022715	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
KANILAD TABLET, FILM COATED 100MG	7275/21T	022714	MEDOCHE MIE LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PULMOTON INHALATION POWDER, PRE-DISPENSED (200+6) MCG/DOSE	8908/21T, 8909/21T	021865	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOG

				RAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PULMOTON INHALATION POWDER, PRE-DISPENSED (400+12) MCG/DOSE	8910/21T, 8911/21T	021866	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PULMOTON INHALATION POWDER, PRE-DISPENSED (100+6) MCG/DOSE	8906/21T, 8907/21T	021864	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur.

				certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LUCIDEL TABLET, FILM COATED 75MG	9258/21T, 9259/21T	021869	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LUCIDEL TABLET, FILM COATED 150MG	9260/21T, 9261/21T	021870	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LUCIDEL TABLET, FILM COATED 300MG	9262/21T, 9263/21T	021871	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/40MG	6784/21T, 6785/21T, 6786/21T	023128	MYLAN IRELAND LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for

				the finished product - Minor changes to an approved test procedure B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/10MG	6787/21T, 6788/21T, 6789/21T	023126	MYLAN IRELAND LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/20MG	6781/21T, 6782/21T, 6783/21T	023127	MYLAN IRELAND LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including

				replacement or addition) B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
LIOTON 1000 GEL 100000IU/100G	3363/21T	013373	A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE SRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
COALIMAX TABLET 40/12.5MG	9462/21T	021923	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
COALIMAX TABLET 80/12.5MG	9461/21T	021924	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
COALIMAX TABLET 80/25MG	9460/21T	021925	DELORBIS PHARMACEUTICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ASACOL SUPPOSITORY 500MG	8609/21T, 8610/21T, 8611/21T	019626	TILLOTTS PHARMA GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of

				Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SEROXAT TABLET, FILM COATED 20MG	7924/21T	014178	GLAXOSMITHKLINE (IRELAND) LIMITED	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
INJOSETRON SOLUTION FOR INJECTION 250MCG/5ML	4934/21T	022576	RAFARM S.A.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SEROXAT TABLET, FILM COATED 20MG	4323/21T	014178	GLAXOSMITHKLINE (IRELAND) LIMITED	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
SEROXAT TABLET, FILM COATED 20MG	1087/21T, 1088/21T	014178	GLAXOSMITHKLINE	A.7 A.7 - ADMINISTRATIVE CHANGES -

			(IRELAND) LIMITED	Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU WITH 10ML SOLVENT	5773/21T, 5774/21T	020331	BAXALTA INNOVATIONS GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU WITH 10ML SOLVENT	5771/21T, 5772/21T	020332	BAXALTA INNOVATIONS GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
RECOMBINATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250IU WITH 10ML SOLVENT	5769/21T, 5770/21T	020330	BAXALTA INNOVATIONS GMBH	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.I.d.1.a.4 B.I.d.1.a.4 -

				QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
BERMOXEL TABLET 600MG	6313/21T, 6314/21T	019838	MEDOCHEMIE LTD	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms
BOCAPRIL TABLET 25MG	9242/21T	023453	MEDOCHEMIE BOHEMIA SPOL. S.R.O.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BOCAPRIL TABLET 50MG	9243/21T	023454	MEDOCHEMIE BOHEMIA SPOL. S.R.O.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TRAVOGEN CREAM 1%	9269/21T, 9270/21T, 9271/21T, 9272/21T	019602	LEO PHARMA A/S	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
TRAVOCORT CREAM	9273/21T, 9274/21T, 9275/21T, 9276/21T	019603	LEO PHARMA A/S	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply

				with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
ALFOXAN SYRUP 50MG/5ML	9327/21T	016070	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ALFOXAN 500 TABLET, FILM COATED 500MG	9326/21T	014417	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

ALFOXAN CAPSULE, HARD 250MG	9328/21T	019924	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BUDENOFALK UNO GASTRO-RESISTANT GRANULES 9MG	3523/21T	022433	DR. FALK PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BUDENOFALK UNO GASTRO-RESISTANT GRANULES 9MG	4946/21T	022433	DR. FALK PHARMA GMBH	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a

				manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
LUCIDEL PLUS TABLET, FILM COATED (300+12.5)MG	9254/21T, 9255/21T	022180	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LUCIDEL PLUS TABLET, FILM COATED (300+25)MG	9256/21T, 9257/21T	022181	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the

				relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LUCIDEL PLUS TABLET, FILM COATED (150+12.5)MG	9252/21T, 9253/21T	022179	ELPEN PHARMACEUTICAL CO INC	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRILEPTAL TABLET, FILM COATED 600MG	9499/21T, 9500/21T, 9501/21T	018464	NOVARTIS IRELAND LIMITED	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules,

				change of needle shield (different plastic used)) - Change that does not affect the product information
SOLPADEINE MAX SOLUBLE EFFERVESCENT TABLET 500MG/30MG/12.8MG	4683/21T, 4684/21T	022825	OMEGA PHARMA HELLAS S.A	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test
SOLPADEINE MAX SOLUBLE EFFERVESCENT TABLET 500MG/30MG/12.8MG	1573/21T, 1574/21T, 1575/21T, 1576/21T, 1577/21T, 1578/21T, 1579/21T, 1580/21T, 1581/21T	022825	OMEGA PHARMA HELLAS S.A	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRILEPTAL TABLET, FILM COATED 300MG	9111/21T, 9112/21T, 9113/21T	018463	NOVARTIS IRELAND LIMITED	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
TARONTAL MODIFIED-RELEASE TABLET 400MG	6582/21T	007154	SANOFI - AVENTIS CYPRUS LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TARONTAL MODIFIED-RELEASE TABLET 400MG	3894/21T	007154	SANOFI - AVENTIS CYPRUS LTD	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including

				batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
FRUMIL TABLET	3895/21T	019400	SANOFI-AVENTIS CYPRUS LTD	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
AFLUON EYE DROPS, SOLUTION 0.05%	8807/21T	021967	MEDA PHARMACEUTICALS S.A.	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LEVOSERT INTRA UTERINE SYSTEM 52MG (20MCG/24h)	4847/21T, 4848/21T	022402	GEDEON RICHTER PLC	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
CILOX TABLET, FILM COATED 400MG	9265/21T	016037	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CILOX TABLET, FILM COATED 200MG	9266/21T	014717	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LAMOSYNT TABLET 200MG	9000/21T, 9001/21T	021490	CODAL-SYNTO LIMITED	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing

				operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LAMOSYNT TABLET 25MG	8998/21T, 8999/21T	021487	CODAL-SYNTO LIMITED	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product -

				Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LAMOSYNT TABLET 100MG	8996/21T, 8997/21T	021489	CODAL-SYNTO LIMITED	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LAMOSYNT TABLET 50MG	8994/21T, 8995/21T	021488	CODAL-SYNTO LIMITED	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product -

				Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	604/21T	019691	NOVARTIS IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	603/21T	019692	NOVARTIS IRELAND LIMITED	C.I.3.a C.I.3.a - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
SRIVASSO INHALATION POWDER, HARD CAPSULE 18MCG	5678/21T, 5679/21T, 5680/21T, 5681/21T, 5682/21T	022341	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method

				is already authorised B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes
ALOPRON TABLET 300MG	8648/21T	019954	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ALOPRON TABLET 100MG	8649/21T	019700	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of

				Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
INFANRIX TETRA SUSPENSION FOR INJECTION	8599/20T, 8600/20T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.4 b) Addition of a new inprocess test and limits
INFANRIX TETRA SUSPENSION FOR INJECTION	1949/21T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
RAFAZIL TABLET, FILM COATED 5MG	9643/21T, 9644/21T	020901	RAFARM S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or

				Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
RAFAZIL TABLET, FILM COATED 10MG	9645/21T, 9646/21T	020900	RAFARM S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
DIVIDOL TABLET, COATED 10MG	8489/21T	019675	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/int

				ermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSUVADOR TABLET, FILM COATED 40MG	5062/21T	022627	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROSUVADOR TABLET, FILM COATED 20MG	5061/21T	022626	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of

				change(s) for which no new additional data is required to be submitted by the MAH
ROSUVADOR TABLET, FILM COATED 5MG	5059/21T	022624	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ROSUVADOR TABLET, FILM COATED 10MG	5060/21T	022625	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DEXAMED ELIXIR ORAL SOLUTION 0.5MG/5ML	9733/21T	020433	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BLOXAZOC TABLET, PROLONGED-RELEASE 50MG	3987/21T, 4951/21T	022741	TAD PHARMA GMBH	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
BLOXAZOC TABLET, PROLONGED-RELEASE 25MG	3986/21T, 4950/21T	022740	TAD PHARMA GMBH	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
BLOXAZOC TABLET, PROLONGED-RELEASE 100MG	3988/21T, 4952/21T	022742	TAD PHARMA GMBH	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
BLOXAZOC TABLET, PROLONGED-RELEASE 200MG	3985/21T, 4949/21T	022743	TAD PHARMA GMBH	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid

				pharmaceutical forms B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
TAVANIC PARENTERAL SOLUTION FOR INFUSION 500MG/100ML	7465/21T	019282	SANOFI - AVENTIS CYPRUS LTD	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	13/21T	023566	AUROBINDO PHARMA (MALTA) LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	14/21T	023563	AUROBINDO PHARMA (MALTA) LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	15/21T	023565	AUROBINDO PHARMA (MALTA) LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	16/21T	023564	AUROBINDO PHARMA (MALTA) LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
VITIS VINIFERA/OPELLA TABLET, FILM COATED 360MG	6686/21T	023393	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally

				Authorised Products
THALIDOMIDE ACCORD CAPSULE, HARD 50MG	7175/21T	023094	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BICOL TABLET, FILM COATED 6.25MG	9248/21T	021340	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
BICOL TABLET, FILM COATED 12.5MG	9249/21T	021341	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
BICOL TABLET, FILM COATED 25MG	9250/21T	021342	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of

				the finished product - Other changes
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	3957/21T	017527	GLAXOSMITHKLINE BIOLOGICALS SA	C.I.1.a C.I.1.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union referral procedure - The medicinal product is covered by the defined scope of the procedure
QUELORAN TABLET, PROLONGED-RELEASE 150MG	5625,5630,5635,564015T	023408	PHARMATHEN S.A.	B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site B.II.b).2.a). Replacement or addition of a site where batch control/testing takes place B.II.b).2.c). 1 Not including b
QUELORAN TABLET, PROLONGED-RELEASE 150MG	5610,5615,5620/15T	023408	PHARMATHEN S.A.	B.II.b.1.a Addition of Hormosan Pharma GmbH as secondary packaging site only for Germany. B.II.b.2.c.1 Addition of Hormosan Pharma GmbH as batch release site not including batch control/testing, only
QUELORAN TABLET, PROLONGED-RELEASE 150MG	5605/15T	023408	PHARMATHEN S.A.	B.II.b).2.c). 1 Not including batch control/testing Addition of: Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany
QUELORAN TABLET, PROLONGED-RELEASE 200MG	5626,5631,5636,5641/15T	023409	PHARMATHEN S.A.	B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site B.II.b).2.a).

				Replacement or addition of a site where batch control/testing takes place B.II.b).2.c). 1 Not including b
QUELORAN TABLET, PROLONGED-RELEASE 200MG	5612,5616,5622/15T	023409	PHARMATHEN S.A.	B.II.b.1.a Addition of Hormosan Pharma GmbH as secondary packaging site only for Germany. B.II.b.2.c.1 Addition of Hormosan Pharma GmbH as batch release site not including batch control/testing, only
QUELORAN TABLET, PROLONGED-RELEASE 200MG	5606/15T	023409	PHARMATHEN S.A.	B.II.b).2.c). 1 Not including batch control/testing Addition of: Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany
QUELORAN TABLET, PROLONGED-RELEASE 300MG	5627,5632,5637,5642/15T	023410	PHARMATHEN S.A.	B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site B.II.b).2.a). Replacement or addition of a site where batch control/testing takes place B.II.b).2.c). 1 Not including b
QUELORAN TABLET, PROLONGED-RELEASE 300MG	5612,5617,5622/15T	023410	PHARMATHEN S.A.	B.II.b.1.a Addition of Hormosan Pharma GmbH as secondary packaging site only for Germany. B.II.b.2.c.1 Addition of Hormosan Pharma GmbH as batch release site not including batch control/testing, only
QUELORAN TABLET, PROLONGED-RELEASE 300MG	5607/15T	023410	PHARMATHEN S.A.	B.II.b).2.c). 1 Not including batch control/testing Addition of: Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany

QUELORAN TABLET, PROLONGED-RELEASE 400MG	5628,5633,5638,5643/15T	023411	PHARMATHEN S.A.	B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site B.II.b).2.a). Replacement or addition of a site where batch control/testing takes place B.II.b).2.c). 1 Not including b
QUELORAN TABLET, PROLONGED-RELEASE 400MG	5613,5618,5623/15T	023411	PHARMATHEN S.A.	B.II.b.1.a Addition of Hormosan Pharma GmbH as secondary packaging site only for Germany. B.II.b.2.c.1 Addition of Hormosan Pharma GmbH as batch release site not including batch control/testing, only
QUELORAN TABLET, PROLONGED-RELEASE 400MG	5608/15T	023411	PHARMATHEN S.A.	B.II.b).2.c). 1 Not including batch control/testing Addition of: Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany
QUELORAN TABLET, PROLONGED-RELEASE 50MG	5624,5629,5634,5639/15T	023407	PHARMATHEN S.A.	B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site B.II.b).2.a). Replacement or addition of a site where batch control/testing takes place B.II.b).2.c). 1 Not including b
QUELORAN TABLET, PROLONGED-RELEASE 50MG	5609,5614,5619/15T	023407	PHARMATHEN S.A.	B.II.b.1.a Addition of Hormosan Pharma GmbH as secondary packaging site only for Germany. B.II.b.2.c.1 Addition of Hormosan Pharma GmbH as batch release site not including batch control/testing, only
QUELORAN TABLET, PROLONGED-RELEASE 50MG	5604/15T	023407	PHARMATHEN S.A.	B.II.b).2.c). 1 Not including batch control/testing Addition of: Salutas Pharma GmbH,

				Otto-von-Guericke Allee 1, 39179 Barleben, Germany
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	4192/20T	013275	PFIZER HELLAS AE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	5855/20T	013275	PFIZER HELLAS AE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	3467/20T	013275	PFIZER HELLAS AE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
FUNGUSTATIN CAPSULE, HARD 150MG	4193/20T	013273	PFIZER HELLAS AE	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
QUELORAN TABLET, PROLONGED-RELEASE 400MG	6197/19T	023411	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
QUELORAN TABLET, PROLONGED-RELEASE 300MG	6196/19T	023410	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
QUELORAN TABLET, PROLONGED-RELEASE 200MG	6195/19T	023409	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including

				contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
QUELORAN TABLET, PROLONGED-RELEASE 150MG	6194/19T	023408	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
QUELORAN TABLET, PROLONGED-RELEASE 50MG	6193/19T	023407	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
FLECTOR TISSUGEL MEDICATED PLASTER 1%	5972-5976/19T	020149	IBSA FARMACEUTICI ITALIA SRL	IA-A.7: deletion of the manufacturing site Laboratoires Genevrier (06600 Antibes – France) as alternative site responsible for quality control and batch release of the finished product. IA- B.I.a.2 a:
QUELORAN TABLET, PROLONGED-RELEASE 400MG	5441/19T	023411	PHARMATHEN S.A.	A.5.b: Change in the name of the site responsible for secondary packaging of the drug product "S.C.F. S.n.c. Di Giovenzana Roberto E Pelizzola Mirko Claudio" to "S.C.F. S.r.l."
QUELORAN TABLET, PROLONGED-RELEASE 300MG	5440/19T	023410	PHARMATHEN S.A.	A.5.b: Change in the name of the site responsible for secondary packaging of the drug product "S.C.F. S.n.c. Di Giovenzana Roberto E Pelizzola Mirko Claudio" to "S.C.F. S.r.l."
QUELORAN TABLET, PROLONGED-RELEASE 200MG	5439/19T	023409	PHARMATHEN S.A.	A.5.b: Change in the name of the site responsible for secondary

				packaging of the drug product "S.C.F. S.n.c. Di Giovenzana Roberto E Pelizzola Mirko Claudio" to "S.C.F. S.r.l."
QUELORAN TABLET, PROLONGED-RELEASE 150MG	5438/19T	023408	PHARMATHEN S.A.	A.5.b: Change in the name of the site responsible for secondary packaging of the drug product "S.C.F. S.n.c. Di Giovenzana Roberto E Pelizzola Mirko Claudio" to "S.C.F. S.r.l."
QUELORAN TABLET, PROLONGED-RELEASE 50MG	5437/19T	023407	PHARMATHEN S.A.	A.5.b: Change in the name of the site responsible for secondary packaging of the drug product "S.C.F. S.n.c. Di Giovenzana Roberto E Pelizzola Mirko Claudio" to "S.C.F. S.r.l."
QUELORAN TABLET, PROLONGED-RELEASE 400MG	1403/19T	023411	PHARMATHEN S.A.	B.III.1.a). 3 New certificate from a new manufacturer (replacement or addition) Type IA, B.III.1.a.3. New certificate from a new manufacturer (replacement or addition)
QUELORAN TABLET, PROLONGED-RELEASE 300MG	1402/19T	023410	PHARMATHEN S.A.	B.III.1.a). 3 New certificate from a new manufacturer (replacement or addition) Type IA, B.III.1.a.3. New certificate from a new manufacturer (replacement or addition)
QUELORAN TABLET, PROLONGED-RELEASE 200MG	1401/19T	023409	PHARMATHEN S.A.	B.III.1.a). 3 New certificate from a new manufacturer (replacement or addition) Type IA, B.III.1.a.3. New certificate from a new manufacturer (replacement or addition)
QUELORAN TABLET, PROLONGED-RELEASE 150MG	1400/19T	023408	PHARMATHEN S.A.	B.III.1.a). 3 New certificate from a new manufacturer (replacement or addition)

				Type IA, B.III.1.a.3. New certificate from a new manufacturer (replacement or addition)
QUELORAN TABLET, PROLONGED-RELEASE 50MG	1399/19T	023407	PHARMATHEN S.A.	B.III.1.a). 3 New certificate from a new manufacturer (replacement or addition) Type IA, B.III.1.a.3. New certificate from a new manufacturer (replacement or addition)
BETAHISTINE AUROBINDO TABLET 8MG	814/19T	023303	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3. z) Other variation to update summary of product characteristics of Betahistine tablets inline with PSUSA wordings (PSUSA/00000389/201712).
SODIUM CHLORIDE/BAXTER(VIAFLO) SOLUTION FOR INFUSION 0.9% W/V	9758/18T	020065	BAXTER (HELLAS) EPE	A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or su
QUELORAN TABLET, PROLONGED-RELEASE 400MG	7756-7757/18T	023411	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 300MG	7754-7755/18T	023410	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the

				Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 200MG	7752-7753/18T	023409	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 150MG	7750-7751/18T	023408	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 50MG	7748-7749/18T	023407	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 400MG	5692/18T	023411	PHARMATHEN S.A.	C.I.3. a) Implementation of wording agreed by the competent authority Regarding PSUSA procedure PSUSA/00002589/201707
QUELORAN TABLET, PROLONGED-RELEASE 300MG	5691/18T	023410	PHARMATHEN S.A.	C.I.3. a) Implementation of wording agreed by the competent authority Regarding PSUSA procedure PSUSA/00002589/201707

QUELORAN TABLET, PROLONGED-RELEASE 200MG	5690/18T	023409	PHARMATHEN S.A.	C.I.3. a) Implementation of wording agreed by the competent authority Regarding PSUSA procedure PSUSA/00002589/201707
QUELORAN TABLET, PROLONGED-RELEASE 150MG	5689/18T	023408	PHARMATHEN S.A.	C.I.3. a) Implementation of wording agreed by the competent authority Regarding PSUSA procedure PSUSA/00002589/201707
QUELORAN TABLET, PROLONGED-RELEASE 50MG	5688/18T	023407	PHARMATHEN S.A.	C.I.3. a) Implementation of wording agreed by the competent authority Regarding PSUSA procedure PSUSA/00002589/201707
SODIUM CHLORIDE/BAXTER(VIAFLO) SOLUTION FOR INFUSION 0.9% W/V	5628/18T	020065	BAXTER (HELLAS) EPE	B.II.e).5.a). 2 Change outside the range of the currently approved pack sizes To add the alternative pack factor of 60 bags per box of 100 ml Sodium chloride 0.9% Solution for Infusion Viaflo produ
QUELORAN TABLET, PROLONGED-RELEASE 400MG	5079/18T	023411	PHARMATHEN S.A.	Type IAin A.1 - Change in the address of the Marketing Authorization Holder in the CMS ES, Apotex Europe B.V. from "Darwinweg 20, 2333 CR, Leiden, The Netherlands" to "Archimedesweg 2, 2333 CN, Leiden
QUELORAN TABLET, PROLONGED-RELEASE 300MG	5078/18T	023410	PHARMATHEN S.A.	Type IAin A.1 - Change in the address of the Marketing Authorization Holder in the CMS ES, Apotex Europe B.V. from "Darwinweg 20, 2333 CR, Leiden, The Netherlands" to

				"Archimedesweg 2, 2333 CN, Leiden
QUELORAN TABLET, PROLONGED-RELEASE 200MG	5077/18T	023409	PHARMATHEN S.A.	Type IAin A.1 - Change in the address of the Marketing Authorization Holder in the CMS ES, Apotex Europe B.V. from "Darwinweg 20, 2333 CR, Leiden, The Netherlands" to "Archimedesweg 2, 2333 CN, Leiden
QUELORAN TABLET, PROLONGED-RELEASE 150MG	5076/18T	023408	PHARMATHEN S.A.	Type IAin A.1 - Change in the address of the Marketing Authorization Holder in the CMS ES, Apotex Europe B.V. from "Darwinweg 20, 2333 CR, Leiden, The Netherlands" to "Archimedesweg 2, 2333 CN, Leiden
QUELORAN TABLET, PROLONGED-RELEASE 50MG	5075/18T	023407	PHARMATHEN S.A.	Type IAin A.1 - Change in the address of the Marketing Authorization Holder in the CMS ES, Apotex Europe B.V. from "Darwinweg 20, 2333 CR, Leiden, The Netherlands" to "Archimedesweg 2, 2333 CN, Leiden
QUELORAN TABLET, PROLONGED-RELEASE 400MG	4199/18T	023411	PHARMATHEN S.A.	B.III.1.a). 1 New certificate from an already approved manufacturer New CEP certificate of the already approved manufacturer of the API Quetiapine fumarate, MOEHS IBÉRICA S.L.
QUELORAN TABLET, PROLONGED-RELEASE 300MG	4198/18T	023410	PHARMATHEN S.A.	B.III.1.a). 1 New certificate from an already approved manufacturer New CEP certificate of the already approved manufacturer of the API Quetiapine fumarate, MOEHS IBÉRICA S.L.
QUELORAN TABLET, PROLONGED-RELEASE 200MG	4197/18T	023409	PHARMATHEN S.A.	B.III.1.a). 1 New certificate from an already approved

				manufacturer New CEP certificate of the already approved manufacturer of the API Quetiapine fumarate, MOEHS IBÉRICA S.L.
QUELORAN TABLET, PROLONGED-RELEASE 150MG	4196/18T	023408	PHARMATHEN S.A.	B.III.1.a). 1 New certificate from an already approved manufacturer New CEP certificate of the already approved manufacturer of the API Quetiapine fumarate, MOEHS IBÉRICA S.L.
QUELORAN TABLET, PROLONGED-RELEASE 50MG	4195/18T	023407	PHARMATHEN S.A.	B.III.1.a). 1 New certificate from an already approved manufacturer New CEP certificate of the already approved manufacturer of the API Quetiapine fumarate, MOEHS IBÉRICA S.L.
QUELORAN TABLET, PROLONGED-RELEASE 400MG	2594-2596/18T	023411	PHARMATHEN S.A.	A.1. Change in the name and/or address of the marketing authorisation holder A.5. a) The activities for which the manufacturer/importer is responsible include batch release A.7. Deletion of manufa
QUELORAN TABLET, PROLONGED-RELEASE 300MG	2591-2593/18T	023410	PHARMATHEN S.A.	A.1. Change in the name and/or address of the marketing authorisation holder A.5. a) The activities for which the manufacturer/importer is responsible include batch release A.7. Deletion of manufa
QUELORAN TABLET, PROLONGED-RELEASE 200MG	2588-2590/18T	023409	PHARMATHEN S.A.	A.1. Change in the name and/or address of the marketing authorisation holder A.5. a) The activities for which

				the manufacturer/importer is responsible include batch release A.7. Deletion of manufa
QUELORAN TABLET, PROLONGED-RELEASE 150MG	2585-2587/18T	023408	PHARMATHEN S.A.	A.1. Change in the name and/or address of the marketing authorisation holder A.5. a) The activities for which the manufacturer/importer is responsible include batch release A.7. Deletion of manufa
QUELORAN TABLET, PROLONGED-RELEASE 50MG	2582-2584/18T	023407	PHARMATHEN S.A.	A.1. Change in the name and/or address of the marketing authorisation holder A.5. a) The activities for which the manufacturer/importer is responsible include batch release A.7. Deletion of manufa
SODIUM CHLORIDE/BAXTER(VIAFLO) SOLUTION FOR INFUSION 0.9% W/V	1685/18T	020065	BAXTER (HELLAS) EPE	C.I. z) Other variation To update sections 4.2, 4.4, 4.5, 4.6, 4.8 of the SmPC and PIL to implement PRAC recommendation EMA/PRAC/406987/2017.
BETAHISTINE AUROBINDO TABLET 8MG	8263/17T	023303	AUROBINDO PHARMA (MALTA) LIMITED	A.2. b) for Nationally Authorised Products to change the name of the medicinal product in Czech Republic from "Betahistin Aurobindo 8 mg/ 16 mg/24 mg tablety" to "Betahistin Aurovitas 8 mg/ 16 mg/24
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	7665/17T	023563	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH

SODIUM CHLORIDE/BAXTER(VIAFLO) SOLUTION FOR INFUSION 0.9% W/V	7395/16T	020065	BAXTER (HELLAS) EPE	B.II.e).5.a). 2 Change outside the range of the currently approved pack sizes To update section 6.5 of the SPC to introduce the alternative pack factor of 75 bags per box of 50 ml Sodium chloride 0.
QUELORAN TABLET, PROLONGED-RELEASE 400MG	4293,4298/16T	023411	PHARMATH EN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3. z) Other variation PSUR update to brand leader
QUELORAN TABLET, PROLONGED-RELEASE 300MG	4292,4297/16T	023410	PHARMATH EN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3. z) Other variation PSUR update to brand leader
QUELORAN TABLET, PROLONGED-RELEASE 200MG	4291,4296/16T	023409	PHARMATH EN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3. z) Other variation PSUR update to brand leader
QUELORAN TABLET, PROLONGED-RELEASE 150MG	4290,4295/16T	023408	PHARMATH EN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.3. z) Other variation PSUR update to brand leader
QUELORAN TABLET, PROLONGED-RELEASE 50MG	4289,4294/16T	023407	PHARMATH EN S.A.	C.I.2. a) Implementation of change(s) for which

				no new additional data is required to be submitted by the MAH C.I.3. z) Other variation PSUR update to brand leader
QUELORAN TABLET, PROLONGED-RELEASE 400MG	6545,6550/15T	023411	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 300MG	6544,6549/15T	023410	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 200MG	6543,6548/15T	023409	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 150MG	6542,6547/15T	023408	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the

				Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 50MG	6541,6546/15T	023407	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 400MG	5598,5603/15T	023411	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 300MG	5597,5602/15T	023410	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 200MG	5596,5601/15T	023409	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 150MG	5595,5600/15T	023408	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a

				summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 50MG	5594,5599/15T	023407	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 400MG	5593/15T	023411	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products Name change in AT. Present: Queloran. Proposed: Quetialan XR
QUELORAN TABLET, PROLONGED-RELEASE 300MG	5592/15T	023410	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products Name change in AT. Present: Queloran. Proposed: Quetialan XR
QUELORAN TABLET, PROLONGED-RELEASE 200MG	5591/15T	023409	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products Name change in AT. Present: Queloran. Proposed: Quetialan XR
QUELORAN TABLET, PROLONGED-RELEASE 150MG	5590/15T	023408	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products Name change in AT. Present: Queloran. Proposed: Quetialan XR
QUELORAN TABLET, PROLONGED-RELEASE 50MG	5589/15T	023407	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products

				Name change in AT. Present: Queloran. Proposed: Quetialan XR
QUELORAN TABLET, PROLONGED-RELEASE 400MG	5117/15T	023411	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
QUELORAN TABLET, PROLONGED-RELEASE 300MG	5116/15T	023410	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
QUELORAN TABLET, PROLONGED-RELEASE 200MG	5115/15T	023409	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
QUELORAN TABLET, PROLONGED-RELEASE 150MG	5114/15T	023408	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
QUELORAN TABLET, PROLONGED-RELEASE 50MG	5113/15T	023407	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location

QUELORAN TABLET, PROLONGED-RELEASE 400MG	2353,2358/15T	023411	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 300MG	2352,2357/15T	023410	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 200MG	2351,2356/15T	023409	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 150MG	2350,2355/15T	023408	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
QUELORAN TABLET, PROLONGED-RELEASE 50MG	2349,2354/15T	023407	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance

				system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System
SODIUM CHLORIDE/BAXTER(VIAFLO) SOLUTION FOR INFUSION 0.9% W/V	4700/14T	020065	BAXTER (HELLAS) EPE	A.1. Change in the name and/or address of the marketing authorisation holder To register a change in address of MA holder- Baxter (Hellas) Ε.Π.Ε, (Greece and Cyprus only) from 3, Metsovou Str., 141
GADOVIST PFS SOLUTION FOR INJECTION IN PREFILLED SYRINGES 1MMOL/ML	7691/22T	022535	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	7690/22T	022534	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EPIDUO GEL (0.001G/0.025G)G	7245/22T	022596	GALDERMA INTERNATIO NAL,FRANCE	A.1. Change in the name and/or address of the marketing authorisation holder A.1 - variation is to correct/standardise the MAH name and address of Ireland on the country specific product information of all the concerned MAs in order to align the name and address as stated in the proof of establishment; GALDERMA INTERNATIONAL, Tour Europlaza, 20, Avenue André Prothin, La Défense 4, 92927 Paris, La Défense, CEDEX, France
EPIDUO GEL (0.001G/0.025G)G	7383/22T	022596	GALDERMA INTERNATIO NAL,FRANCE	A.1. Change in the name and/or address of the marketing

				authorisation holder A.1 - Change in the address of the marketing authorisation holder Galderma (U.K.) Limited, from 69-71 Clarendon Road, Watford, Herts, WD17 1DS, UK to Evergreen House North, Grafton Place, London, England, NW1 2DX. United Kingdom
ROZOR TABLET, FILM COATED 20MG/10MG	7797/22T	022905	MYLAN IRE HEALTHCAR E LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation MAT:FROM MYLAN IRE HEALTHCARE LIMITED to VIATRIS HEALTHCARE LIMITED.
ROZOR TABLET, FILM COATED 10MG/10MG	7796/22T	022904	MYLAN IRE HEALTHCAR E LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation MAT:FROM MYLAN IRE HEALTHCARE LIMITED to VIATRIS HEALTHCARE LIMITED.
EZETIMIBE/MYLAN TABLET 10MG	7940/22T	023155	MYLAN IRELAND LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
EZETIMIBE+SIMVASTATIN /MYLAN TABLET 10MG/10MG	null	023126	MYLAN IRELAND LIMITED	A.2. b) for Nationally Authorised Products in ES->new: Ezetimiba/Simvasta tina Viatris 10 mg/20 mg, 10 mg/40 mg comprimidos EFG affects only 10/20 & 10/40
INFANRIX TETRA SUSPENSION FOR INJECTION	5599/22T, 5600/22T	020232	GLAXOSMI THKLINE BIOLOGICAL S SA	B.I.b).1. b) Tightening of specification limits B.II.d).1. f) Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product

				Handled as procedure type IB
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 54MG	1324/22T	021507	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 36MG	1323/22T	021506	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
METHYLPHENIDATE HCL SANDOZ TABLET, PROLONGED-RELEASE 18MG	1322/22T	021505	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	2662/22T	022534	BAYER HELLAS ABEE	B.III.1.a). 1 New certificate from an already approved manufacturer New CEP R0-CEP 2017-275-Rev 01 for the active substance gadobutrol monohydrate, issue date 13.08.2019 CEP-holder: Bayer AG, Kaiser Wilhlem Allee 1, Germany 51373 Leverkusen Site of production: Bayer AG, Ernst-Schering-Strasse 14, Germany 59192 Bergkamen Production of intermediate(s): Dynamit Nobel GmbH, Explosivstoff- und Systemtechnik, Kalkstrasse 218, Germany 51377 Leverkusen
GADOVIST PFS SOLUTION FOR INJECTION IN PREFILLED SYRINGES 1MMOL/ML	2663/22T	022535	BAYER HELLAS ABEE	B.III.1.a). 1 New certificate from an already approved manufacturer New CEP R0-CEP 2017-275-Rev 01 for the active substance gadobutrol monohydrate, issue date 13.08.2019

				CEP-holder: Bayer AG, Kaiser Wilhlem Allee 1, Germany 51373 Leverkusen Site of production: Bayer AG, Ernst-Schering-Strasse 14, Germany 59192 Bergkamen Production of intermediate(s): Dynamit Nobel GmbH, Explosivstoff- und Systemtechnik, Kalkstrasse 218, Germany 51377 Leverkusen
LOPINAVIR/RITONAVIR ACCORD TABLET, FILM COATED 200/50MG	2795/22	022723	ACCORD HEALTHCARE S.L.U	A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* Deletion of Hetero Malta Limited responsible for Importation of Finished product of Lopinavir/ Ritonavir Accord 200 mg / 50 mg Film coated Tablets.
EZETIMIBE SANDOZ TABLET 10MG	1325/22T	022118	SANDOZ GMBH	A.1. Change in the name and/or address of the marketing authorisation holder Change in the address of the Marketing Authorization Holder "1 A Pharma GmbH" from "Keltenring 1+3, 82041 Oberhaching, Germany" to "Industriestraße 18, 83607 Holzkirchen, Germany".
FEIBA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 25U/ML	153/22T, 154/22T, 155/22T, 156/22T, 157/22T	022343	BAXALTA INNOVATIONS GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES -

				Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsibl
NOSATEL TABLET, FILM COATED 25MG	3372 - 3380/18T	020154	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	Partially approved B.II.d).1. d) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) B.II.d).2. b) Deletion of a test procedure if an alternative method is already authorised B.II.d).2. d) Other changes to a test procedure (including replacement or addition) B.II.d.2.d x 6 B.II.d.1.d x 2 B.II.d.2.b x 1
VALSARTAN JUBILANT TABLET, FILM COATED 320MG	9839/21T - 9842/21T	022498	JUBILANT PHARMACEUTICALS NV	B.I.b).1. h) Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result

				of a safety or quality issue B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a.2) Submission of an updated Ph.Eur certificate of suitability, R1-CEP 2011-110-Rev 01, for valstartan from Jubilant Generics Limited. B.III.1.a.2) Submission of an updated Ph.Eur certificate of suitability, R1-CEP 2011-110
ROSUVADOR TABLET, FILM COATED 20MG	9177/21T	022626	TAD PHARMA GMBH	B.II.b).1. e) Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products Krka, d.d., Novo mesto would like to add Ningbo Menovo Tiankang Pharmaceuticals Co., Ltd.,China as bulk manufacturing site for Rosuvastatin 5 mg, 10 mg and 20 mg film-coated tablets.
ROSUVADOR TABLET, FILM COATED 10MG	9176/21T	022625	TAD PHARMA GMBH	B.II.b).1. e) Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products Krka, d.d., Novo mesto would like to add Ningbo Menovo Tiankang Pharmaceuticals Co., Ltd.,China as bulk manufacturing site for Rosuvastatin 5 mg,

				10 mg and 20 mg film-coated tablets.
ROSUVADOR TABLET, FILM COATED 5MG	9175/21T	022624	TAD PHARMA GMBH	B.II.b).1. e) Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products Krka, d.d., Novo mesto would like to add Ningbo Menovo Tiankang Pharmaceuticals Co., Ltd.,China as bulk manufacturing site for Rosuvastatin 5 mg, 10 mg and 20 mg film-coated tablets.
ROSUVADOR TABLET, FILM COATED 40MG	9171/21T	022627	TAD PHARMA GMBH	B.II.f).1.b). 1 As packaged for sale (supported by real time data) We would like to extend the shelf-life for Rosuvastatin 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg film-coated tablets from 24-months to 36-months. We are filling this variation because the stability testing results that prove the shelf life of the finished product (for Rosuvastatin 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg film-coated tablets tablets) of 36 months are available.
ROSUVADOR TABLET, FILM COATED 20MG	9172/21T	022626	TAD PHARMA GMBH	B.II.f).1.b). 1 As packaged for sale (supported by real time data) We would like to extend the shelf-life for Rosuvastatin 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg film-coated tablets from 24-months to 36-months. We are filling this variation because the stability testing results that prove

				the shelf life of the finished product (for Rosuvastatin 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg film-coated tablets tablets) of 36 months are available.
ROSUVADOR TABLET, FILM COATED 10MG	9173/2021T	022625	TAD PHARMA GMBH	B.II.f).1.b). 1 As packaged for sale (supported by real time data) We would like to extend the shelf-life for Rosuvastatin 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg film-coated tablets from 24-months to 36-months. We are filling this variation because the stability testing results that prove the shelf life of the finished product (for Rosuvastatin 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg film-coated tablets tablets) of 36 months are available.
ROSUVADOR TABLET, FILM COATED 5MG	9174/21T	022624	TAD PHARMA GMBH	B.II.f).1.b). 1 As packaged for sale (supported by real time data) We would like to extend the shelf-life for Rosuvastatin 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg film-coated tablets from 24-months to 36-months. We are filling this variation because the stability testing results that prove the shelf life of the finished product (for Rosuvastatin 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg film-coated tablets tablets) of 36 months are available.
ROSUVADOR TABLET, FILM COATED 40MG	9167/21T	022627	TAD PHARMA GMBH	In June 2017 new information was noticed in SmPC of the reference product, referring to Heterozygous Familial

				Hypercholesterole mia in paediatric patients. New information was added in Sections 4.1, 4.2, 5.1 and 5.2. Our documents (SmPC/PIL/CCDS) should be updated. Please note that within this variation procedure we also made editorial correction: we renate Anhydrous from the name of excipient, as according to the latest Ph. Monograph for excipients. Please find updated corresponding documenta
ROSUVADOR TABLET, FILM COATED 20MG	9168/21T	022626	TAD PHARMA GMBH	In June 2017 new information was noticed in SmPC of the reference product, referring to Heterozygous Familial Hypercholesterole mia in paediatric patients. New information was added in Sections 4.1, 4.2, 5.1 and 5.2. Our documents (SmPC/PIL/CCDS) should be updated. Please note that within this variation procedure we also made editorial correction: we renate Anhydrous from the name of excipient, as according to the latest Ph. Monograph for excipients. Please find updated corresponding documenta
ROSUVADOR TABLET, FILM COATED 10MG	9169/21T	022625	TAD PHARMA GMBH	In June 2017 new information was noticed in SmPC of the reference product, referring to Heterozygous Familial Hypercholesterole mia in paediatric patients. New information was

				added in Sections 4.1, 4.2, 5.1 and 5.2. Our documents (SmPC/PIL/CCDS) should be updated. Please note that within this variation procedure we also made editorial correction: we renate Anhydrous from the name of excipient, as according to the latest Ph. Monograph for excipients. Please find updated corresponding documenta
ROSUVADOR TABLET, FILM COATED 5MG	9170/21T	022624	TAD PHARMA GMBH	In June 2017 new information was noticed in SmPC of the reference product, referring to Heterozygous Familial Hypercholesterolemia in paediatric patients. New information was added in Sections 4.1, 4.2, 5.1 and 5.2. Our documents (SmPC/PIL/CCDS) should be updated. Please note that within this variation procedure we also made editorial correction: we renate Anhydrous from the name of excipient, as according to the latest Ph. Monograph for excipients. Please find updated corresponding documenta
IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	6010-6011/20T	023259	ACCORD HEALTHCARE LIMITED	B.II.b.2.a. - for addition of Batch testing Site i.e. Wessling Hungary Kft, Hungary for captioned product. B.II.b.2.c.1. - for addition of Accord Healthcare Polska Sp.z.o.o, Poland as batch release site responsible for importation/batch release for captioned product

TESTOGEL GEL 50MG	2444/20T	020520	LABORATOIRES BESINS INTERNATIONAL	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
TESTOGEL GEL 25MG	2445/20T	020590	LABORATOIRES BESINS INTERNATIONAL	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	1758/20T	022522	ACCORD HEALTHCARE LIMITED	C.I.1. a) The medicinal product is covered by the defined scope of the procedure Type IB variation (C.I.1.a) to update SmPC, PIL and Labelling information in-line with the agreed wordings of Article 31 referral outcome for methotrexate containing products published on EC
FLECTOR TISSUGEL MEDICATED PLASTER 1%	1650/20T	020149	IBSA FARMACEUTICI ITALIA SRL	A.2. b) CHANGE THE PRODUCT NAME IN POLAND
EZETIMIBE SANDOZ TABLET 10MG	11441/19T	022118	SANDOZ GMBH	B.I.a).1. b) Introduction of a manufacturer of the active.Introduction of Zhejiang Tianyu Pharmaceutical Co., Ltd., China as manufacturer of the active substance supported by an ASMF
MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	1416-1417/19T	017107	PFIZER HELLAS AE	A.4. Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites) A.5. b) The activities for which the manufacturer/importer is responsible do not include batch release

				IA-A.4 : Change in the address of a supplier of the active substance responsible for the manufacture and packaging of sterile meropenem trihydrate drug substance and sterile sodium carbonate excipient:ACS Dobfar S.p.A. (Italy) IA-A.5.b.: Change in the address of the manufactur
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	9353/19T	013275	PFIZER HELLAS AE	C.I. z) Other variation To update section 4.5 of the Summary of Product Characteristics (SmPC) and section 2 of the Package Leaflet (PL) with information regarding drug-drug interaction between fluconazole and ibrutinib in line with the French Medical Interaction Thesaurus (published in May 2018).
FUNGUSTATIN CAPSULE, HARD 150MG	9352/19T	013273	PFIZER HELLAS AE	C.I. z) Other variation To update section 4.5 of the Summary of Product Characteristics (SmPC) and section 2 of the Package Leaflet (PL) with information regarding drug-drug interaction between fluconazole and ibrutinib in line with the French Medical Interaction Thesaurus (published in May 2018).
IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	9212/19T	023259	ACCORD HEALTHCARE LIMITED	B.II.b).1. a) Secondary packaging site addition of Accord Healthcare Limited, Edgefield Avenue, Newcastle Upon Tyne, NE3 3NB,

				United Kingdom as additional secondary packaging site for Idarubicin
FUNGUSTATIN CAPSULE, HARD 150MG	8546/19T	013273	PFIZER HELLAS AE	A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* Deletion of a manufacturer for batch control/testing, packaging and batch release: "FAMAR A.V.E. Anonymous Industrial Company of Pharmaceuticals & Cosmetics Anthoussa Plant, 7 Anthoussa Avenue, Greece-15349 Anthou
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	8545/19T	013275	PFIZER HELLAS AE	A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* Deletion of a manufacturer for batch control/testing, packaging and batch release: "Famar S.A., 63 Agiou Demetriou Str., Greece-17456 Alimos, Athens".
FLUOXETINE AUROBINDO CAPSULE, HARD 20MG	7278/19T	023333	AUROBINDO PHARMA	C.I. z) Other variation to update Summary

			(MALTA) LIMITED	of Product Characteristics and Patient leaflet for Fluoxetine Aurobindo 20 mg and 60 mg capsules, hard with reference to the recommendations by PRAC (Doc ref: EMA/PRAC/265221 /2019).
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	7114-7118/19T	019692	NOVARTIS IRELAND LIMITED	A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site B.II.b).2.a). Replacement or addition of a site where batch control/testing takes place B.II.b).2.c). 1 Not including batch control/t
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	7109-7113/19T	019691	NOVARTIS IRELAND LIMITED	A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site B.II.b).2.a). Replacement or addition of a site

				where batch control/testing takes place B.II.b).2.c). 1 Not including batch control/t
EXEDRAL 25 TABLET, FILM COATED 25MG	6784/19T	022057	REMEDICA LTD	B.I.b).2. a) Minor changes to an approved test procedure • Updated information in Solubility section in compliance with Ph. Eur. 5.11 / Ph. Eur. General Notices.
SYNTOPAR TABLET 40MG	6597/19T	020198	CODAL SYNTO LTD	C.I. z) PRAC recommendations
SYNTOPAR TABLET 30MG	6596/19T	020197	CODAL SYNTO LTD	C.I. z) PRAC recommendations
SYNTOPAR TABLET 20MG	6595/19T	020196	CODAL SYNTO LTD	C.I. z) PRAC recommendations
SYNTOPAR TABLET 10MG	6594/19T	020195	CODAL SYNTO LTD	C.I. z) PRAC recommendations
SYNTOPAR TABLET 40MG	4305-4307/19T	020198	CODAL SYNTO LTD	A.7.Klocke Verpackungs-Service GmbH,as well as the manufacturing site responsible for primary/secondary packaging and batch release Hormosan Pharma GmbH will be deleted B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site
SYNTOPAR TABLET 30MG	4302-4304/19T	020197	CODAL SYNTO LTD	A.7.Klocke Verpackungs-Service GmbH,as well as the manufacturing site responsible for primary/secondary packaging and batch release Hormosan Pharma GmbH will be deleted B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site
SYNTOPAR TABLET 20MG	4299-4301	020196	CODAL SYNTO LTD	A.7.Klocke Verpackungs-Service GmbH,as well as the manufacturing site responsible for primary/secondary packaging and batch release

				Hormosan Pharma GmbH will be deleted B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site
SYNTOPAR TABLET 10MG	4296-4298/19T	020195	CODAL SYNTO LTD	A.7.Klocke Verpackungs-Service GmbH,as well as the manufacturing site responsible for primary/secondary packaging and batch release Hormosan Pharma GmbH will be deleted B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site
EXEDRAL 25 TABLET, FILM COATED 25MG	3173-3175/19T	022057	REMEDICA LTD	B.I.b).1. b) Tightening of specification limits B.III.1.a). 1 New certificate from an already approved manufacturer B.III.2.b). Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.1.a.1) Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance - New certificate from an already approved manufacturer. The manufacturer Qilu Antibiotics
NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	2867-2868/19T	021972	RAFARM S.A.	B.II.b).2.c). 1 Not including batch control/testing B.II.b.2.c.1.: Addition of "STADA Arzneimittel AG, Stadastraße 2-18, 61118 Bad Vilbel, Germany" as manufacturer for batch release. B.II.b.2.c.1.:

				Addition of "STADAPHARM GmbH" as manufacturer for batch release. Headquarter: Stadastraße 2-18, 61118 Bad Vilbel, Germany Manufacturing Site: Feodor-Lynen-Straße 35, 30625 Hannover, Germany
FLECTOR TISSUGEL MEDICATED PLASTER 1%	2698/19T	020149	IBSA FARMACEUTICI ITALIA SRL	A.2 b) concerning the product name change in Germany only
TACROLIMUS ACCORD OINTMENT 0.1%	2188-2190/19T	023599	ACCORD HEALTHCARE LIMITED	3B.II.b).2.c). 1 Not including batch control/testing B.II.d).2. a) Minor changes to an approved test procedure B.II.b.2.c.1 (2x) - For addition of "Mibe GmbH Arzneimittel", Germany as batch release site responsible for importation and/or batch release - For addition of "Accord Healthcare Polska Sp. z.o.o", Poland as batch release site responsible for importation and/or batch release B.II.d.2.a - For minor change in approved test procedure of 'Related Substances and Content of Tautomers' (=
NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	1499 - 1500/19T	021972	RAFARM S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location

				due to MA transfer in DE to ALIUD PHARMA GmbH: in DE->new: Zoledronsäure AL 4 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung in DE->new: Introduction of PSMF Stada Arzneimittel AG including all affiliates [MFL539]; location: STADA Arzneimittel AG, Stadastr.
NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	1495/19T	021972	RAFARM S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH Adaptation of the SPC and PIL to reference product Zometa (EU/1/01/176/004-006) and to the current QRD template; furthermore editorial changes
MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	671/19T	017107	PFIZER HELLAS AE	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. Update section 4.8 of the meropenem Summary of Product Characteristics (SmPC) by adding a new adverse drug reaction (ADR) “Delirium” with an assigned frequency category of “Rare”
DOVOBET OINTMENT	30/19T	019618	LEO PHARMA A/S	B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a.2 Updated certificate from an already approved

				manufacturer TEVA Pharmaceutical Industries applied for a Minor Revision of the CEP and CEP R1-CEP 2000-223 rev. 05 was granted on February 22, 2018.
QLAIRA TABLET, FILM COATED	9714/18T	020525	BAYER HELLAS ABEE	C.I.z Other variation
TACROLIMUS ACCORD OINTMENT 0.1%	9129-9130/18T	023599	ACCORD HEALTHCARE LIMITED	1A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location 1) To change the product name in Germany from Tacrolimus Accord 1mg/g Salbe to Tacrolimus Dermapharm 1 mg/g Salbe. 2) To propose new PSMF in Germany and updated PSMF for Accord.
SKUDEXA GRANULES FOR ORAL SOLUTION 75MG/25MG	8031/18T	023030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.I.a).1. a) The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
SYNTOPAR TABLET 40MG	7907/18T	020198	CODAL SYNTO LTD	C.I.3. a) Update the SmPC and PIL following the PRAC
SYNTOPAR TABLET 30MG	7906/18T	020197	CODAL SYNTO LTD	C.I.3. a) Update the SmPC and PIL following the PRAC
SYNTOPAR TABLET 20MG	7905/18T	020196	CODAL SYNTO LTD	C.I.3. a) Update the SmPC and PIL following the PRAC
SYNTOPAR TABLET 10MG	7904/18T	020195	CODAL SYNTO LTD	C.I.3. a) Update the SmPC and PIL following the PRAC
FUNGUSTATIN CAPSULE, HARD 150MG	6019-6020/18T	013273	PFIZER HELLAS AE	C.I. z) Other variation To update the product texts of

				(SmPC, Package Leaflet and Labelling) with a warning on sodium. In addition: - Update to section 6.1 of the SmPCs and corresponding sections of PIL and labelling to add E numbers for gelatin, black iron oxide, propylene glycol, potassium hydroxide (Diflucan capsules), Xanthan gum, Sodium benzoate (Diflucan Powder for Oral Suspension), Glycerol and Citric acid monohydrate (Diflucan Syrup). - Update to section 5 of the PLs of Diflucan Powder
SYNTOPAR TABLET 40MG	6066/18T	020198	CODAL SYNTO LTD	C.I.4.Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data.
SYNTOPAR TABLET 30MG	6065/18T	020197	CODAL SYNTO LTD	C.I.4.Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data.
SYNTOPAR TABLET 20MG	6064/18T	020196	CODAL SYNTO LTD	C.I.4.Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data.
SYNTOPAR TABLET 10MG	6063/18T	020195	CODAL SYNTO LTD	C.I.4.Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data.
FLUOXETINE AUROBINDO CAPSULE, HARD 20MG	5263/18T	023333	AUROBINDO PHARMA (MALTA) LIMITED	A.2. b) for Nationally Authorised Products A.2.b. - to transfer of the Marketing Authorisation Holder of Fluoxetine

				Aurobindo 20 mg capsules, hard in Czech Republic from Aurobindo Pharma (Malta) Limited, Malta to Aurovitas Pharma Polska Sp. z o.o., Poland, we propose to change the name of the medicinal product in Czech Republic from "Fluoxetine Aurobindo 20 mg Tvrdé tobolky" to "Fluoxetine Aurovitas".
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	2825-2826/18T	019692	NOVARTIS IRELAND LIMITED	C.I.3. z) Other variation C.I.11. z) Other variation
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	2823-2824/18T	019691	NOVARTIS IRELAND LIMITED	C.I.3. z) Other variation C.I.11. z) Other variation
DOVOBET OINTMENT	2374/18T	019618	LEO PHARMA A/S	C.I.3. z) Other variation This Type 1B, C.I.3.z variation worksharing procedure concerns the planned update of the Product Information for the above listed LEO products containing corticosteroids. The changes are being made in accordance with PRAC's recommendation for Budesonide (PSUSA/00000449/ 201604), which in January 2017 has been extended by CMDh to all corticosteroid containing products (all formulations). This worksharing procedure will include 298 MAs (17 product formulations; three o
TACROLIMUS ACCORD OINTMENT 0.1%	2527-2529/18T	023599	ACCORD HEALTHCAR E S.L.U	2 B.II.d).1. d) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or

				identification test for a colouring or flavouring material) B.III.1.a). 1 New certificate from an already approved manufacturer B.III.2.a). 1 Active substance 1. To register the deletion of the non-significant test parameter, Extractable Weight from the specifications of the finished product. 2. To register the addition of the European Pharmacopoeia Certif
PENEMNIA POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	2473/18T	022318	PHARMATHEN S.A.	with IE/H/1091/001-002/IB/016, R/001
FLUOXETINE AUROBINDO CAPSULE, HARD 20MG	1752/18T	023333	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.a. - to bring the product information of Fluoxetine 20 mg and 60 mg capsules, hard in line with the product information of reference medicinal product i.e., Prozac 20 mg hard capsules.
MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	1093/18T	017107	PFIZER HELLAS AE	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. Update section 4.8 of the SmPC to add acute generalized exanthematous pustulosis (AGEP) and section 4.4 of the SmPC with regard to AGEP and severe cutaneous adverse

				reactions (SCAR) such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and erythema multif
NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	1033/18T	021972	RAFARM S.A.	C.I.3. a) Implementation of wording agreed by the competent authority Adaptation in SPC sections 4.4., 4.8 and PIL section 4 "warning on osteonecrosis of other anatomical sites". [- PSUSA-modification EMEA/H/C/PSUSA/3149/201608; close date procedure 19.06.2017; active substance "zoledronic acid (indicated for cancer and fractures)". - Brussels, 16.6.2017; C(2017) 4314 final; COMMISSION IMPLEMENTING DECISION of 16.6.2017 concerning, in the framework of article 107e of directive 2001/83/EC of th
MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	9139-9142/17T	017107	PFIZER HELLAS AE	A.4. Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites) B.II.b).1. a) Secondary packaging site B.II.b).2.c). 1 Not including batch control/testing B.II.e).6. b) Change that does not affect the product information A.4 : Administrative change to the name

				of the sterilization site responsible for the irradiation of bulk powder packaging components from Bioster S.p.A to STERIS S.p.A. B.II.b.1.a : Addition of Zambon Switzerland Ltd as a
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	5817/17T	013275	PFIZER HELLAS AE	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. To add Drug-Drug Interaction information between fluconazole and tofacitinib in section 4.5 of the Summary of Product Characteristics (SmPC) in line with the company's Core Data Sheet (CDS) following approval of the Marketing Authorisation Application for Xeljanz (tofacitinib) in Europe on 22nd March 2017. Including amendment of section
FUNGUSTATIN CAPSULE, HARD 150MG	5816/17T	013273	PFIZER HELLAS AE	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. To add Drug-Drug Interaction information between fluconazole and tofacitinib in section 4.5 of the Summary of Product Characteristics (SmPC) in line with

				the company's Core Data Sheet (CDS) following approval of the Marketing Authorisation Application for Xeljanz (tofacitinib) in Europe on 22nd March 2017. Including amendment of section
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	5922/17T	019692	NOVARTIS IRELAND LIMITED	B.II.f).1.d). Change in storage conditions of the finished product or the diluted/reconstituted product
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	5921/17T	019691	NOVARTIS IRELAND LIMITED	B.II.f).1.d). Change in storage conditions of the finished product or the diluted/reconstituted product
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	2494/17T	013275	PFIZER HELLAS AE	C.I. z) Other variation Implementation of PRAC signal recommendation: [Article 5 recommendation; 01.07.2013]: PRAC signals on the meeting at 06 to 09 February 2017 (EMA/PRAC/68642/2017) English version, (EMA/PRAC/113479/2017) German version, concerning Fluconazole (EPITT-Nr. 18666: Spontaneous abortion and stillbirth, SPC section 4.6., PIL is not affected).
FUNGUSTATIN CAPSULE, HARD 150MG	2493/17T	013273	PFIZER HELLAS AE	C.I. z) Other variation Implementation of PRAC signal recommendation: [Article 5 recommendation; 01.07.2013]: PRAC signals on the meeting at 06 to 09 February 2017 (EMA/PRAC/68642/2017) English version, (EMA/PRAC/113479/2017) German

				version, concerning Fluconazole (EPITT-Nr. 18666: Spontaneous abortion and stillbirth, SPC section 4.6., PIL is not affected).
FUNGUSTATIN SOLUTION FOR INFUSION 100MG/50ML	1449-1453/17T	013275	PFIZER HELLAS AE	C.I. z) Other variation C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. To update the following sections of the SmPC and PL in line with the MAH's Company Core Data Sheet (CCDS): · update text from “regular dialysis” to “hemodialysis" in section 4.2 of the SmPC · update sections 4.4. and 4.5 of the SmPC with text regarding fluconazole and cytochrome P450 (CYP) isozymes
FUNGUSTATIN CAPSULE, HARD 150MG	1444-1448/17T	013273	PFIZER HELLAS AE	C.I. z) Other variation C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. To update the following sections of the SmPC and PL in line with the MAH's Company Core Data Sheet (CCDS): · update text from “regular dialysis” to “hemodialysis" in section 4.2 of the SmPC · update sections 4.4. and 4.5 of the

				SmPC with text regarding fluconazole and cytochrome P450 (CYP) isozymes · update se
FLUOXETINE AUROBINDO CAPSULE, HARD 20MG	1544/17T	023333	AUROBINDO PHARMA (MALTA) LIMITED	B.II.f).1.b). 1 As packaged for sale (supported by real time data) To extend shelf-life of the finished product, from 2 years to 3 years.
NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	8765-67/16T	021972	RAFARM S.A.	C.I. z) Other variation C.I.3. z) Other variation - Implementation of the agreed wording of PRAC recommendation (EMA/PRAC/590265/2015) - Adjustment of SPC and PIL according to EMEA/H/C/PSUSA/3149/201308 - Adjustment of SPC and PIL according to EMEA/H/C/PSUSA/00003149/201508
AMINOPLASMAL B. BRAUN 10% E SOLUTION FOR INFUSION 100G/L	7505-35/16T	022836	B. BRAUN MELSUNGEN AG	B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a). 3 New certificate from a new manufacturer (replacement or addition) B.III.1.a). 4 Deletion of certificates (in case multiple certificates exist per material)
MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	616/16T	017107	PFIZER HELLAS AE	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. DRESS add section 4.8
SYNTOPAR TABLET 40MG	7320/15T	020198	CODAL SYNTO LTD	C.I.2. a) Update the SmPC and PIL with some more amendments in line

				with the originator's (Seroxat)
SYNTOPAR TABLET 30MG	7319/15T	020197	CODAL SYNTO LTD	C.I.2. a) Update the SmPC and PIL with some more amendments in line with the originator's (Seroxat)
SYNTOPAR TABLET 20MG	7318/15T	020196	CODAL SYNTO LTD	C.I.2. a) Update the SmPC and PIL with some more amendments in line with the originator's (Seroxat)
SYNTOPAR TABLET 10MG	7317/15T	020195	CODAL SYNTO LTD	C.I.2. a) Update the SmPC and PIL with some more amendments in line with the originator's (Seroxat)
SYNTOPAR TABLET 40MG	2482/15T	020198	CODAL SYNTO LTD	C.I. z) Update the SmPC and PIL following the outcome of a PRAC signal recommendation
SYNTOPAR TABLET 30MG	2481/15T	020197	CODAL SYNTO LTD	C.I. z) Update the SmPC and PIL following the outcome of a PRAC signal recommendation
SYNTOPAR TABLET 20MG	2480/15T	020196	CODAL SYNTO LTD	C.I. z) Update the SmPC and PIL following the outcome of a PRAC signal recommendation
SYNTOPAR TABLET 10MG	2479/15T	020195	CODAL SYNTO LTD	C.I. z) Update the SmPC and PIL following the outcome of a PRAC signal recommendation
MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	4697/14T	017107	PFIZER HELLAS AE	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. implement change made to meropenem CDS in June 2013. The change concerns section 4.6 Pregnancy and lactation: Statement on lactation revised as a case of meropenem

				excreted in breast milk has been reported.
MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	4226,4228,4230/14T	017107	PFIZER HELLAS AE	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. Section 5.3 Pre-clinical safety data: Statement on a preliminary study in monkeys has been deleted.
MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	3503,3505/14T	017107	PFIZER HELLAS AE	C.I.3. a) Implementation of wording agreed by the competent authority
AMINOPLASMAL B. BRAUN 10% E SOLUTION FOR INFUSION 100G/L	10198-10229/13T	022836	B. BRAUN MELSUNGEN AG	A.4. Change in the name and/or address of: a manufacturer A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient B.II.d).2. a) Minor changes to an approved test procedure B.II.e).7. b) Replacement or addition of a supplier B.III.1.a). 1 B.III.1.a). 2 B.III.1.a). 3
INFANRIX TETRA SUSPENSION FOR INJECTION	5599/22T, 5600/22T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).1. b) Tightening of specification limits B.II.d).1. f) Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product

				Handled as procedure type IB
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8020/21T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).1. z) Other variation
INFANRIX TETRA SUSPENSION FOR INJECTION	8019/21T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).1. z) Other variation
INFANRIX TETRA SUSPENSION FOR INJECTION	6861/22T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b).5. z) Other variation
ENGERIX-B SUSPENSION FOR INJECTION 20MCG/1ML	6857/22T	012941	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b).5. z) Other variation
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	6864/22T	017527	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b).5. z) Other variation
HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	6859/22T	016694	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b).5. z) Other variation
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	6863/22T	018647	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b).5. z) Other variation
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	6865/22T	022907	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b).5. z) Other variation
ENGERIX-B PEDIATRIC SUSPENSION FOR INJECTION 10MCG/0.5ML	6856/22T	012940	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b).5. z) Other variation
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	6862/22T	020252	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b).5. z) Other variation
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	6860/22T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b).5. z) Other variation
HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	6858/22T	017849	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.b).5. z) Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	2761/22T, 2762/22T	019159	SANOFI-AVENTIS GROUPE	B.I.b).2. e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.II.d).2. d) Other changes to a test procedure (including replacement or addition)

				The purpose of this variation application submitted herewith is to implement a Chromogenic kinetic method for endotoxin determination in alternative to gel clot method. The current gel clot method limit test (Ph. Eur. 2.6.14 method A) is a pass or fail type with no possibility to have monitoring of the level of endotoxins in the API or the water system. Implementing Chromogenic kinetic method (Ph. Eur. 2.6.14 method D) will allow quantification with very low level of quantification allowing close monitoring and trending, as well as, implementing action if required to lower down the amount of endotoxins before it fails the limit test.
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	2765/22T, 2766/22T	019744	SANOFI-AVENTIS GROUPE	B.I.b).2. e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.II.d).2. d) Other changes to a test procedure (including replacement or addition) The purpose of this variation application submitted herewith is to implement a Chromogenic kinetic method for endotoxin determination in alternative to gel clot method. The current gel clot method limit test (Ph. Eur. 2.6.14 method A) is a pass

				or fail type with no possibility to have monitoring of the level of endotoxins in the API or the water system. Implementing Chromogenic kinetic method (Ph. Eur. 2.6.14 method D) will allow quantification with very low level of quantification allowing close monitoring and trending, as well as, implementing action if required to lower down the amount of endotoxins before it fails the limit test.
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	2763/22T, 2764/22T	019160	SANOFI-AVENTIS GROUPE	B.I.b).2. e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.II.d).2. d) Other changes to a test procedure (including replacement or addition) The purpose of this variation application submitted herewith is to implement a Chromogenic kinetic method for endotoxin determination in alternative to gel clot method. The current gel clot method limit test (Ph. Eur. 2.6.14 method A) is a pass or fail type with no possibility to have monitoring of the level of endotoxins in the API or the water system. Implementing Chromogenic kinetic method (Ph. Eur. 2.6.14 method D) will allow quantification with very low level of quantification

				allowing close monitoring and trending, as well as, implementing action if required to lower down the amount of endotoxins before it fails the limit test.
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	2767/22T, 2768/22T	019161	SANOFI-AVENTIS GROUPE	B.I.b).2. e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.II.d).2. d) Other changes to a test procedure (including replacement or addition) The purpose of this variation application submitted herewith is to implement a Chromogenic kinetic method for endotoxin determination in alternative to gel clot method. The current gel clot method limit test (Ph. Eur. 2.6.14 method A) is a pass or fail type with no possibility to have monitoring of the level of endotoxins in the API or the water system. Implementing Chromogenic kinetic method (Ph. Eur. 2.6.14 method D) will allow quantification with very low level of quantification allowing close monitoring and trending, as well as, implementing action if required to lower down the amount of endotoxins before it fails the limit test.

PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	2278/22T, 2279/22T, 2280/22T	019080	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	2278/22T, 2279/22T, 2280/22T	019080	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PROGRAF CAPSULE, HARD 1MG	2284/22T, 2285/22T, 2286/22T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PROGRAF CAPSULE, HARD 1MG	2284/22T, 2285/22T, 2286/22T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PROGRAF CAPSULE, HARD 5MG	2281/22T, 2282/22T, 2283/22T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PROGRAF CAPSULE, HARD 5MG	2281/22T, 2282/22T, 2283/22T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PROGRAF CAPSULE, HARD 0.5MG	2275/22T, 2276/22T, 2277/22T	022365	ASTELLAS PHARMACEU	C.I.4. Change(s) in the Summary of

			TICALS A.E.B.E.	Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PROGRAF CAPSULE, HARD 0.5MG	2275/22T, 2276/22T, 2277/22T	022365	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	9408/22T, 9409/22T, 9410/22T	021496	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a.2. Updated CEP from [R1-CEP 2013-268 Rev 01] to [R1-CEP 2013-268 Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Zhejiang Tianyu Pharmaceutical Co., Ltd". B.III.1.a.2. Updated CEP from [R1-CEP 2013-105-Rev 01] to [R1-CEP 2013-105-Rev 02] for the acitve substance "olmesartan medoxomil" from an already approved manufacturer "Chinoin". CEP holder: name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest"

				remains the same. Site of production name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd" to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. B.III.1.a.2. Updated CEP from [R1-CEP 2012-398-Rev 01] to [R1-CEP 2012-398-Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Daiichi Sankyo". Production of intermediate(s): name changed from: "CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO., LTD." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.

ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	9411/22T, 9412/22T, 9413/22T	021495	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a.2. Updated CEP from [R1-CEP 2013-268 Rev 01] to [R1-CEP 2013-268 Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Zhejiang Tianyu Pharmaceutical Co., Ltd". B.III.1.a.2. Updated CEP from [R1-CEP 2013-105-Rev 01] to [R1-CEP 2013-105-Rev 02] for the acitve substance "olmesartan medoxomil" from an already approved manufacturer "Chinoin". CEP holder: name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. Site of production name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd" to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.

				B.III.1.a.2. Updated CEP from [R1-CEP 2012-398-Rev 01] to [R1-CEP 2012-398-Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Daiichi Sankyo". Production of intermediate(s): name changed from: "CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO., LTD." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.
ORIZAL PLUS TABLET, FILM COATED 40/10/12.5MG	9414/22T, 9415/22T, 9416/22T	021494	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a.2. Updated CEP from [R1-CEP 2013-268 Rev 01] to [R1-CEP 2013-268 Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Zhejiang Tianyu Pharmaceutical Co., Ltd". B.III.1.a.2. Updated CEP from [R1-CEP 2013-105-Rev 01] to [R1-CEP 2013-105-Rev 02] for the acitve substance "olmesartan medoxomil" from an already approved

				manufacturer "Chinoin". CEP holder: name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. Site of production name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd" to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. B.III.1.a.2. Updated CEP from [R1-CEP 2012-398-Rev 01] to [R1-CEP 2012-398-Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Daiichi Sankyo". Production of intermediate(s): name changed from: "CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO., LTD." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.

ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	9417/22T, 9418/22T, 9419/22T	021493	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a.2. Updated CEP from [R1-CEP 2013-268 Rev 01] to [R1-CEP 2013-268 Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Zhejiang Tianyu Pharmaceutical Co., Ltd". B.III.1.a.2. Updated CEP from [R1-CEP 2013-105-Rev 01] to [R1-CEP 2013-105-Rev 02] for the acitve substance "olmesartan medoxomil" from an already approved manufacturer "Chinoin". CEP holder: name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. Site of production name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd" to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.

				B.III.1.a.2. Updated CEP from [R1-CEP 2012-398-Rev 01] to [R1-CEP 2012-398-Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Daiichi Sankyo". Production of intermediate(s): name changed from: "CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO., LTD." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	9420/22T, 9421/22T, 9422/22T	021492	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a.2. Updated CEP from [R1-CEP 2013-268 Rev 01] to [R1-CEP 2013-268 Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Zhejiang Tianyu Pharmaceutical Co., Ltd". B.III.1.a.2. Updated CEP from [R1-CEP 2013-105-Rev 01] to [R1-CEP 2013-105-Rev 02] for the acitve substance "olmesartan medoxomil" from an already approved

				manufacturer "Chinoin". CEP holder: name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. Site of production name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd" to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. B.III.1.a.2. Updated CEP from [R1-CEP 2012-398-Rev 01] to [R1-CEP 2012-398-Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Daiichi Sankyo". Production of intermediate(s): name changed from: "CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO., LTD." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.

ORIZAL TABLET, FILM COATED 40MG/10MG	9423/22T, 9424/22T, 9425/22T	020614	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a.2. Updated CEP from [R1-CEP 2013-268 Rev 01] to [R1-CEP 2013-268 Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Zhejiang Tianyu Pharmaceutical Co., Ltd". B.III.1.a.2. Updated CEP from [R1-CEP 2013-105-Rev 01] to [R1-CEP 2013-105-Rev 02] for the acitve substance "olmesartan medoxomil" from an already approved manufacturer "Chinoin". CEP holder: name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. Site of production name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd" to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.

				B.III.1.a.2. Updated CEP from [R1-CEP 2012-398-Rev 01] to [R1-CEP 2012-398-Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Daiichi Sankyo". Production of intermediate(s): name changed from: "CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO., LTD." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.
ORIZAL TABLET, FILM COATED 40MG/5MG	9426/22T, 9427/22T, 9428/22T	020613	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a.2. Updated CEP from [R1-CEP 2013-268 Rev 01] to [R1-CEP 2013-268 Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Zhejiang Tianyu Pharmaceutical Co., Ltd". B.III.1.a.2. Updated CEP from [R1-CEP 2013-105-Rev 01] to [R1-CEP 2013-105-Rev 02] for the acitve substance "olmesartan medoxomil" from an already approved

				manufacturer "Chinoin". CEP holder: name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. Site of production name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd" to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. B.III.1.a.2. Updated CEP from [R1-CEP 2012-398-Rev 01] to [R1-CEP 2012-398-Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Daiichi Sankyo". Production of intermediate(s): name changed from: "CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO., LTD." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.

ORIZAL TABLET, FILM COATED 20MG/5MG	9429/22T, 9430/22T, 9431/22T	020612	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a). 2 Updated certificate from an already approved manufacturer B.III.1.a.2. Updated CEP from [R1-CEP 2013-268 Rev 01] to [R1-CEP 2013-268 Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Zhejiang Tianyu Pharmaceutical Co., Ltd". B.III.1.a.2. Updated CEP from [R1-CEP 2013-105-Rev 01] to [R1-CEP 2013-105-Rev 02] for the acitve substance "olmesartan medoxomil" from an already approved manufacturer "Chinoin". CEP holder: name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same. Site of production name changed from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd." to: "EUROAPI HUNGARY Ltd." from: "CHINOIN Pharmaceutical and Chemical Works Private Co., Ltd" to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.

				B.III.1.a.2. Updated CEP from [R1-CEP 2012-398-Rev 01] to [R1-CEP 2012-398-Rev 02] for the active substance "olmesartan medoxomil" from an already approved manufacturer "Daiichi Sankyo". Production of intermediate(s): name changed from: "CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO., LTD." to: "EUROAPI HUNGARY Ltd." the address: "To Utca 1-5, Hungary-1045 Budapest" remains the same.
SUBUTEX TABLET, SUBLINGUAL 0.4MG	5546/22T, 5547/22T, 5548/22T, 5549/22T, 5550/22T, 5551/22T, 5552/22T, 5553/22T	020071	INDIVIOR EUROPE LIMITED	A.4. Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites) B.I.b).1. c) Addition of a new specification parameter to the specification with its corresponding test method B.I.b).1. z) Other variation B.I.b).2. a) Minor changes to an approved test procedure B.I.b).2. b) Deletion of a test procedure for the active substance or a starting material/reagent/ intermediate, if an alternative test procedure is already authorised. B.I.b).2. e) Other changes to a test procedure (including

				replacement or addition) for the active substance or a starting material/intermediate
SUBUTEX TABLET, SUBLINGUAL 8MG	5530/22T, 5531/22T, 5532/22T, 5533/22T, 5534/22T, 5535/22T, 5536/22T, 5537/22T	020073	INDIVIOR EUROPE LIMITED	A.4. Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites) B.I.b).1. c) Addition of a new specification parameter to the specification with its corresponding test method B.I.b).1. z) Other variation B.I.b).2. a) Minor changes to an approved test procedure B.I.b).2. b) Deletion of a test procedure for the active substance or a starting material/reagent/ intermediate, if an alternative test procedure is already authorised. B.I.b).2. e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
SUBUTEX TABLET, SUBLINGUAL 2MG	5538/22T, 5539/22T, 5540/22T, 5541/22T, 5542/22T, 5543/22T, 5544/22T, 5545/22T	020072	INDIVIOR EUROPE LIMITED	A.4. Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites) B.I.b).1. c) Addition of a new specification parameter to the specification with its corresponding test method

				B.I.b).1. z) Other variation B.I.b).2. a) Minor changes to an approved test procedure B.I.b).2. b) Deletion of a test procedure for the active substance or a starting material/reagent/ intermediate, if an alternative test procedure is already authorised. B.I.b).2. e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediat e
SYNTOSARTIN TABLET 300MG	8708/22T	020977	CODAL-SYNTO LIMITED	B.II.b.3.a. - QUALITY CHANGES – FINISHED PRODUCT - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: **minor changes in the manufacturing process at Medo-A central factory, which are related to new equipment available at this manufacturing site.**
SYNTOSARTIN TABLET 150MG	8709/22T	020976	CODAL-SYNTO LIMITED	B.II.b.3.a. - QUALITY CHANGES – FINISHED PRODUCT - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: **minor changes in the manufacturing process at Medo-A central factory, which are related to new equipment available at this**

				manufacturing site.
INFANRIX TETRA SUSPENSION FOR INJECTION	5936/22T, 5937/22T, 5938/22T, 5939/22T, 5940/22T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).4. b) Addition of a new in-process test and limits B.I.b).1. b) Tightening of specification limits B.I.b).1. e) Deletion of a specification parameter which may have a significant effect on the overall quality of the active substance and/or the finished product B.I.b).1. z) Other variation B.I.b).2. a) Minor changes to an approved test procedure
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	5931/22T, 5932/22T, 5933/22T, 5934/22T, 5935/22T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).4. b) Addition of a new in-process test and limits B.I.b).1. b) Tightening of specification limits B.I.b).1. e) Deletion of a specification parameter which may have a significant effect on the overall quality of the active substance and/or the finished product B.I.b).1. z) Other variation B.I.b).2. a) Minor changes to an approved test procedure
PROGRAF CAPSULE, HARD 5MG	5917/22T, 5918/22T	019079	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.I.a).2. e) Minor change to the restricted part of an Active Substance Master File
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	5911/22T, 5912/22T	019080	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.I.a).2. e) Minor change to the restricted part of an Active Substance Master File
PROGRAF CAPSULE, HARD 1MG	5915/22T, 5916/22T	019081	ASTELLAS PHARMACEUTICALS A.E.B.E.	B.I.a).2. e) Minor change to the restricted part of an Active Substance Master File
PROGRAF CAPSULE, HARD 0.5MG	5913/22T, 5914/22T	022365	ASTELLAS PHARMACEU	B.I.a).2. e) Minor change to the restricted part of an

			TICALS A.E.B.E.	Active Substance Master File
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	2470/22T, 2471/22T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).2. d) Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance
INFANRIX TETRA SUSPENSION FOR INJECTION	2472/22T, 2473/22T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).2. d) Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	5602/22T	019523	SANOFI PASTEUR.	B.II.d).2. c) Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	5601/22T	022511	SANOFI PASTEUR.	B.II.d).2. c) Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol
ENGERIX-B SUSPENSION FOR INJECTION 20MCG/1ML	5923/22T, 5924/22T, 5925/22T, 5926/22T	012941	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS
ENGERIX-B SUSPENSION FOR INJECTION 20MCG/1ML	5923/22T, 5924/22T, 5925/22T, 5926/22T	012941	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS
ENGERIX-B PEDIATRIC SUSPENSION FOR INJECTION 10MCG/0.5ML	5919/22T, 5920/22T, 5921/22T, 5922/22T	012940	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.4.a - Change to in-process tests or limits applied during

				the manufacture of the AS
ENGERIX-B PEDIATRIC SUSPENSION FOR INJECTION 10MCG/0.5ML	5919/22T, 5920/22T, 5921/22T, 5922/22T	012940	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS
TRAVOGEN CREAM 1%	4054/15T	019602	LEO PHARMA A/S	C.I.4 - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data – Update SPC & PIL
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	2450/22T, 2451/22T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).2. a) Minor change in the manufacturing process of the active substance B.I.a).2. c) The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol B.I.a.2.a variation is handled as a IB type of procedure.
INFANRIX TETRA SUSPENSION FOR INJECTION	2452/22T, 2453/22T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).2. a) Minor change in the manufacturing process of the active substance B.I.a).2. c) The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal

				product and is not related to a protocol B.I.a.2.a variation is handled as a IB type of procedure.
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	3442/22T, 3443/22T	019523	SANOFI PASTEUR.	B.I.b).1. c) Addition of a new specification parameter to the specification with its corresponding test method B.I.b).2. z) [DEPRECATED] Other variation B.I. b) 2. z) handled as a Type IB Unforeseen variation
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	3444/22T, 3445/22T	022511	SANOFI PASTEUR.	B.I.b).1. c) Addition of a new specification parameter to the specification with its corresponding test method B.I.b).2. z) [DEPRECATED] Other variation B.I. b) 2. z) handled as a Type IB Unforeseen variation
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8304/21T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
INFANRIX TETRA SUSPENSION FOR INJECTION	8305/21T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	2454/22T	019523	SANOFI PASTEUR.	B.I.b).1. z) Other variation IB unforeseen
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	2455/22T	022511	SANOFI PASTEUR.	B.I.b).1. z) Other variation IB unforeseen

TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	2323/22T	022511	SANOFI PASTEUR.	B.II.c).1. z) Other variation
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	2324/22T	019523	SANOFI PASTEUR.	B.II.c).1. z) Other variation
TIENAM POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	9658/21T	021719	MERCK SHARP & DOHME BV	B.II.g).2. Introduction of a post approval change management protocol related to the finished product
TIENAM POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	9658/21T	021719	MERCK SHARP & DOHME BV	B.II.g).2. Introduction of a post approval change management protocol related to the finished product
TIENAM POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	9658/21T	021719	MERCK SHARP & DOHME BV	B.II.g).2. Introduction of a post approval change management protocol related to the finished product
ESMERON SOLUTION FOR INJECTION 50MG/5ML	9657/21T	018110	MSD AFVEE	B.II.g).2. Introduction of a post approval change management protocol related to the finished product
ESMERON SOLUTION FOR INJECTION 50MG/5ML	9657/21T	018110	MSD AFVEE	B.II.g).2. Introduction of a post approval change management protocol related to the finished product
ESMERON SOLUTION FOR INJECTION 50MG/5ML	9657/21T	018110	MSD AFVEE	B.II.g).2. Introduction of a post approval change management protocol related to the finished product
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	439/22T, 440/22T, 441/22T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).2. d) Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance Quality
INFANRIX TETRA SUSPENSION FOR INJECTION	436/22T, 437/22T, 438/22T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).2. d) Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a

				method using a biological reagent for a biological active substance Quality
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8014/21T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).2. a) Minor change in the manufacturing process of the active substance
INFANRIX TETRA SUSPENSION FOR INJECTION	8015/21T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).2. a) Minor change in the manufacturing process of the active substance
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	425/22T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.d).1. z) Other variation Quality
INFANRIX TETRA SUSPENSION FOR INJECTION	424/22T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.d).1. z) Other variation Quality
INFANRIX TETRA SUSPENSION FOR INJECTION	423/22T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).2. a) Minor change in the manufacturing process of the active substance Quality
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8017/21T	020324	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).1. j) Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place
INFANRIX TETRA SUSPENSION FOR INJECTION	8018/21T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).1. j) Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place
INFANRIX TETRA SUSPENSION FOR INJECTION	83/22T	020232	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).2. a) Minor change in the manufacturing process of the active substance

PHYSIONEAL 35 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	null	022309	BAXTER (HELLAS) EPE	B.II.e).1.b). 3 Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form B.II.e).4. c) Sterile medicinal products B.II.e).6. b) Change that does not affect the product information B.III.2.z). Other variation B.III.2.z:The reference to the current version of Ph. Eur. monograph 3.1.6 for inner and outer layers of the primary film is introduced with this variation. B.II.e.4.c:The Master batch is no longer used for the production of the inner layer of the primary film, therefore a deletion of the “Master batch” is proposed. BII.e.6.b: Due to initial production issues with the peelable film (top layer of 95 µm), the content of Polyamide has been increased, which resulted in increased thickness of top layer (106 µm). B.II.e.1.b.3: The Lineo connector is included in the currently approved dossier as an alternate connector for CAPD bags. This type of connector is no longer used, and is not planned to be used in the future.

IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	6008-6009/20T	023261	ACCORD HEALTHCARE LIMITED	B.II.b).2.a). Replacement or addition of a site where batch control/testing takes place B.II.b).2.c). 1 Not including batch control/testing B.II.b.2.a. - for addition of Batch testing Site i.e. Wessling Hungary Kft, Hungary for captioned product. B.II.b.2.c.1. - for addition of Accord Healthcare Polska Sp.z.o.o, Poland as batch release site responsible for importation/batch release for captioned product
SYNTOPAR TABLET 40MG	5960-5962/20T	020198	CODAL SYNTO LTD	A.1. Change in the name and/or address of the marketing authorisation holder A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a). 2 Updated certificate from an already approved manufacturer A.1. - Change in the name and/or address of the marketing Autorisation Holder in Cyprus, Codal-Synto Ltd. A.7. - Deletion of API manufacturing site Aesica Pharmaceuticals Limited. B.III.1.a). 2 -

				Submission of updated CEP of the already approved API manufacturer Zheijang Huahai Pharmaceutical Co (R1-CEP 2006-002-Rev01).
SYNTOPAR TABLET 30MG	5963-5965/20T	020197	CODAL SYNTO LTD	A.1. Change in the name and/or address of the marketing authorisation holder A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a). 2 Updated certificate from an already approved manufacturer A.1. - Change in the name and/or address of the marketing Autorisation Holder in Cyprus, Codal-Synto Ltd. A.7. - Deletion of API manufacturing site Aesica Pharmaceuticals Limited. B.III.1.a). 2 - Submission of updated CEP of the already approved API manufacturer Zheijang Huahai Pharmaceutical Co (R1-CEP 2006-002-Rev01).

SYNTOPAR TABLET 20MG	5966-5968/20T	020196	CODAL SYNTO LTD	A.1. Change in the name and/or address of the marketing authorisation holder A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a). 2 Updated certificate from an already approved manufacturer A.1. - Change in the name and/or address of the marketing Autorisation Holder in Cyprus, Codal-Synto Ltd. A.7. - Deletion of API manufacturing site Aesica Pharmaceuticals Limited. B.III.1.a). 2 - Submission of updated CEP of the already approved API manufacturer Zheijang Huahai Pharmaceutical Co (R1-CEP 2006-002-Rev01).
SYNTOPAR TABLET 10MG	5969-5971/20T	020195	CODAL SYNTO LTD	A.1. Change in the name and/or address of the marketing authorisation holder A.7. Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or

				supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a). 2 Updated certificate from an already approved manufacturer A.1. - Change in the name and/or address of the marketing Autorisation Holder in Cyprus, Codal-Synto Ltd. A.7. - Deletion of API manufacturing site Aesica Pharmaceuticals Limited. B.III.1.a). 2 - Submission of updated CEP of the already approved API manufacturer Zheijang Huahai Pharmaceutical Co (R1-CEP 2006-002-Rev01).
CERTICAN TABLET 1MG	10800/19T	019645	NOVARTIS IRELAND LIMITED	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. The variation concerns an update of efficacy and safety data of the 12 months paediatric kidney transplantation study (A2314; n=106) with subsequent 24 months follow up data (36 months study period total). The Type II Variation involves an update of section 5.1, with consequential changes to section 4.2 (and 4.8).

CERTICAN TABLET 0.75MG	10799/19T	019644	NOVARTIS IRELAND LIMITED	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. The variation concerns an update of efficacy and safety data of the 12 months paediatric kidney transplantation study (A2314; n=106) with subsequent 24 months follow up data (36 months study period total). The Type II Variation involves an update of section 5.1, with consequential changes to section 4.2 (and 4.8).
CERTICAN TABLET 0.5MG	10798/19T	019643	NOVARTIS IRELAND LIMITED	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. The variation concerns an update of efficacy and safety data of the 12 months paediatric kidney transplantation study (A2314; n=106) with subsequent 24 months follow up data (36 months study period total). The Type II Variation involves an update of section 5.1, with consequential changes to section 4.2 (and 4.8).

CERTICAN TABLET 0.25MG	10797/19T	019642	NOVARTIS IRELAND LIMITED	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. The variation concerns an update of efficacy and safety data of the 12 months paediatric kidney transplantation study (A2314; n=106) with subsequent 24 months follow up data (36 months study period total). The Type II Variation involves an update of section 5.1, with consequential changes to section 4.2 (and 4.8).
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	9667/19T	023566	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH to update the product information in line with innovator product 'Topamax' (SE/H/0110/001-004)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	9666/19T	023565	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH to update the product information in line with innovator product 'Topamax' (SE/H/0110/001-004)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	9665/19T	023564	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH to update the

				product information in line with innovator product 'Topamax' (SE/H/0110/001-004)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	9664/19T	023563	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH to update the product information in line with innovator product 'Topamax' (SE/H/0110/001-004)
MEDSAMIC SOLUTION FOR INJECTION 100MG/ML	9586/19T	021959	MEDOCHEMIE LTD	B.III.1.a). 5 New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free B.III.1.a.5) New certificate, R0-CEP 2018-048-Rev 00, for tranexamic acid from Shilpa Medicare Limited; Plot No. 33, 33A, 40 to 47; Raichur Industrial Growth Centre; Wadloor Road; Chicksugur Cross; Chicksugur; 584 134 Raichur; Karnataka; India. Certificate holder is Shilpa Medicare Limited, No.12-6-214/A1, Hyderabad Road, 584 135 Raichur, Karnataka, India. A risk management summary for elemental impurities is appended.
MEDSAMIC SOLUTION FOR INJECTION 100MG/ML	9587/19T	021959	MEDOCHEMIE LTD	B.I.d).1.a). 4 Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4) Introduction of a retest period of 2

				years for tranexamic acid manufactured by Shilpa Medicare Limited.
LAMIVUDINE/ZIDOVUDINE ACCORD TABLET, FILM COATED 150MG/300MG	9354/19T	023309	ACCORD HEALTHCARE LIMITED	C.I. z) Other variation SCOPE: We wish to submit a Type II (C.I.z) variation application.To update the SmPC and PIL of Lamivudine/Zidovudine 150 mg/300 mg film-coated tablets in line with the commitment during RUP. Furthermore, MAH take this opportunity to update PI as per reference product text i.e., Combivir 150 mg/300 mg film-coated tablets of ViiV Healthcare UK Limited. BACKGROUND: The captioned product has been approved through Decentralized Procedure PT/H/0972/001/DC. With this variation application, we wish to submit a Type II (C.I.z) variation application to update the SmPC and PIL of Lamivudine/Zidovudine 150 mg/300 mg film-coated tablets in line with the commitment during RUP. Further more, MAH take this opportunity to update PI as per reference product text i.e., Combivir 150 mg/300 mg film-coated tablets of ViiV Healthcare UK Limited. Copy of commitment letter as well as reference product text is enclosed for ready reference.

FORADIL INHALATION POWDER, HARD CAPSULE 12MCG	9358-9363/19T	018494	NOVARTIS IRELAND LIMITED	B.II.b.1.c - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes – Addition of the finished product manufacturing site Novartis Farmaceutica S.A.B.II.b.3.a - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product
IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	9213/19T	023261	ACCORD HEALTHCARE LIMITED	B.II.b).1. a) Secondary packaging site addition of Accord Healthcare Limited, Edgefield Avenue, Newcastle Upon Tyne, NE3 3NB, United Kingdom as additional secondary packaging site for Idarubicin 5mg/5ml, 10mg/10ml & 20mg/20ml solution for injection.
IDARUBICIN ACCORD SOLUTION FOR INJECTION 10MG/10ML	9211/19T	023260	ACCORD HEALTHCARE LIMITED	B.II.b).1. a) Secondary packaging site addition of Accord Healthcare Limited, Edgefield Avenue, Newcastle Upon Tyne, NE3 3NB, United Kingdom as

				additional secondary packaging site for Idarubicin 5mg/5ml, 10mg/10ml & 20mg/20ml solution for injection.
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	9137/19T	023566	AUROBINDO PHARMA (MALTA) LIMITED	B.II.e).5.a). 2 Change outside the range of the currently approved pack sizes To add a new pack size of 30 blisters
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	9136/19T	023565	AUROBINDO PHARMA (MALTA) LIMITED	B.II.e).5.a). 2 Change outside the range of the currently approved pack sizes To add a new pack size of 30 blisters
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	9135/19T	023564	AUROBINDO PHARMA (MALTA) LIMITED	B.II.e).5.a). 2 Change outside the range of the currently approved pack sizes To add a new pack size of 30 blisters
STREPFEN ORANGE SUGAR FREE LOZENGE 8.75MG	8933-8934/19T	021793	RECKITT BENCKISER HELLAS CHEMICAL ABEE	A.1. Change in the name and/or address of the marketing authorisation holder Change in the name of Greek MAH from RECKITT BENCKISER HELLAS CHEMICALS ABEE to RECKITT BENCKISER HELLAS HEALTHCARE SA.
RIDOCA CAPSULE, HARD 250MG	8818/19T	022135	AENORASIS SA	C.I.3. a) Implementation of wording agreed by the competent authority update section 4.8 of Summary of Product Characteristics (SmPC) of Ridoca, hard caps, 5/20/100/140/180 & 250mg/cap and implement the PRAC Signals Recommendations on "Drug reaction with eosinophilia and systemic symptoms (DRESS)" adopted at the 11-14 June 2019 PRAC Meeting (see

				Attachment 1: EMA/PRAC/303951 /2019).
RIDOCA CAPSULE, HARD 180MG	8817/19T	022134	AENORASI S SA	C.I.3. a) Implementation of wording agreed by the competent authority update section 4.8 of Summary of Product Characteristics (SmPC) of Ridoca, hard caps, 5/20/100/140/180 & 250mg/cap and implement the PRAC Signals Recommendations on "Drug reaction with eosinophilia and systemic symptoms (DRESS)" adopted at the 11-14 June 2019 PRAC Meeting (see Attachment 1: EMA/PRAC/303951 /2019).
RIDOCA CAPSULE, HARD 140MG	8816/19T	022133	AENORASI S SA	C.I.3. a) Implementation of wording agreed by the competent authority update section 4.8 of Summary of Product Characteristics (SmPC) of Ridoca, hard caps, 5/20/100/140/180 & 250mg/cap and implement the PRAC Signals Recommendations on "Drug reaction with eosinophilia and systemic symptoms (DRESS)" adopted at the 11-14 June 2019 PRAC Meeting (see Attachment 1: EMA/PRAC/303951 /2019).
RIDOCA CAPSULE, HARD 100MG	8815/19T	022132	AENORASI S SA	C.I.3. a) Implementation of wording agreed by the competent authority update section 4.8 of Summary of Product

				Characteristics (SmPC) of Ridoca, hard caps, 5/20/100/140/180 & 250mg/cap and implement the PRAC Signals Recommendations on "Drug reaction with eosinophilia and systemic symptoms (DRESS)" adopted at the 11-14 June 2019 PRAC Meeting (see Attachment 1: EMA/PRAC/303951 /2019).
RIDOCA CAPSULE, HARD 20MG	8814/19T	022131	AENORASIS SA	C.I.3. a) Implementation of wording agreed by the competent authority update section 4.8 of Summary of Product Characteristics (SmPC) of Ridoca, hard caps, 5/20/100/140/180 & 250mg/cap and implement the PRAC Signals Recommendations on "Drug reaction with eosinophilia and systemic symptoms (DRESS)" adopted at the 11-14 June 2019 PRAC Meeting (see Attachment 1: EMA/PRAC/303951 /2019).
RIDOCA CAPSULE, HARD 5MG	8813/19T	022130	AENORASIS SA	C.I.3. a) Implementation of wording agreed by the competent authority update section 4.8 of Summary of Product Characteristics (SmPC) of Ridoca, hard caps, 5/20/100/140/180 & 250mg/cap and implement the PRAC Signals Recommendations on "Drug reaction with eosinophilia and systemic symptoms (DRESS)" adopted at the 11-14 June

				2019 PRAC Meeting (see Attachment 1: EMA/PRAC/303951 /2019).
SEVELAMER CARBONATE SANDOZ TABLET, FILM COATED 800MG	8587/19T	022154	SANDOZ GMBH	C.I.3. a) Implementation of wording agreed by the competent authority We would like to apply for a change in PiL and SmPC regarding Sevelamer Carbonate, Film-coated tablets and Powder for Oral Suspension, in order to implement the EC decision, regarding EMEA/H/C/PSUSA/ 00002697/201810.
RIDOCA CAPSULE, HARD 250MG	8324/19T	022135	AENORASI S SA	B.III.2.b). Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State To implement the changes as per current Ph. Eur. monograph of Temozolomide (Ph. Eur. version 9.7). The ASMF has been updated to version 7.1 (2019-07-18).
RIDOCA CAPSULE, HARD 180MG	8323/19T	022134	AENORASI S SA	B.III.2.b). Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State To implement the changes as per current Ph. Eur. monograph of Temozolomide (Ph. Eur. version 9.7). The ASMF has been updated to version 7.1 (2019-07-18).
RIDOCA CAPSULE, HARD 140MG	8322/19T	022133	AENORASI S SA	B.III.2.b). Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a

				Member State To implement the changes as per current Ph. Eur. monograph of Temozolomide (Ph. Eur. version 9.7). The ASMF has been updated to version 7.1 (2019-07-18).
RIDOCA CAPSULE, HARD 100MG	8321/19T	022132	AENORASIS SA	B.III.2.b). Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State To implement the changes as per current Ph. Eur. monograph of Temozolomide (Ph. Eur. version 9.7). The ASMF has been updated to version 7.1 (2019-07-18).
RIDOCA CAPSULE, HARD 20MG	8320/19T	022131	AENORASIS SA	B.III.2.b). Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State To implement the changes as per current Ph. Eur. monograph of Temozolomide (Ph. Eur. version 9.7). The ASMF has been updated to version 7.1 (2019-07-18).
RIDOCA CAPSULE, HARD 5MG	8919/19T	022130	AENORASIS SA	B.III.2.b). Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State To implement the changes as per current Ph. Eur. monograph of Temozolomide (Ph. Eur. version 9.7). The ASMF has been updated to version 7.1 (2019-07-18).

TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	7982/19T	023566	AUROBINDO PHARMA (MALTA) LIMITED	C.I. z) Other variation update product information to the recommendations by PRAC EMA/PRAC/303951/2019
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	7981/19T	023565	AUROBINDO PHARMA (MALTA) LIMITED	C.I. z) Other variation update product information to the recommendations by PRAC EMA/PRAC/303951/2019
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	7980/19T	023564	AUROBINDO PHARMA (MALTA) LIMITED	C.I. z) Other variation update product information to the recommendations by PRAC EMA/PRAC/303951/2019
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	7979/19T	023563	AUROBINDO PHARMA (MALTA) LIMITED	C.I. z) Other variation update product information to the recommendations by PRAC EMA/PRAC/303951/2019
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.3MG/ML	7241-7242/19T	022780	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location The scope of the present grouped variation is the notification of change, due to an ongoing MA transfer in member state ES, of the (invented) name of the medicinal product to INN+MAH name, for ES only, under variation classification A.2.b. (please refer to annex-519 in section 1.2 and common PIL in

				section 1.3.1). Additionally, the summary of pharmacovigilance system of the new MAH in ES is introduced via variation classification C.I.8.a. (enclosed in section 1.8.1).
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.1MG/ML	7239-7240/19T	022779	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location The scope of the present grouped variation is the notification of change, due to an ongoing MA transfer in member state ES, of the (invented) name of the medicinal product to INN+MAH name, for ES only, under variation classification A.2.b. (please refer to annex-519 in section 1.2 and common PIL in section 1.3.1). Additionally, the summary of pharmacovigilance system of the new MAH in ES is introduced via variation classification C.I.8.a. (enclosed in section 1.8.1).
ACTONEL OAW TABLET, FILM COATED 35MG	5413/19T	019723	ACTAVIS GROUP PTC EHF	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance

				System Master File (PSMF) location The Marketing Authorisation Holder has submitted a signed Summary of the MAH's Pharmacovigilance System. Provided that the Pharmacovigilance System Master File fully complies with the new legal requirements as set out in the Commission Implementing Regulation and as detailed in the GVP module, the Summary is considered acceptable.
IMATINIB/MYLAN TABLET, FILM COATED 400MG	5280/19T	023473	MYLAN S.A.S.	C.I.3. a) Implementation of wording agreed by the competent authority implemantation of the PSUSA/00001725/ 201805
IMATINIB/MYLAN TABLET, FILM COATED 100MG	5279/19T	023472	MYLAN S.A.S.	C.I.3. a) Implementation of wording agreed by the competent authority implemantation of the PSUSA/00001725/ 201805
IDARUBICIN ACCORD SOLUTION FOR INJECTION 10MG/10ML	3793-3794/19T	023260	ACCORD HEALTHCARE LIMITED	B.II.b).2.a). Replacement or addition of a site where batch control/testing takes place B.II.b).2.c). 1 Not including batch control/testing B.II.b.2.a. - for addition of Batch testing Site i.e. Wessling Hungary Kft, Hungary for captioned product. B.II.b.2.c.1. - for addition of Accord Healthcare Polska Sp.z.o.o, Poland as batch release site responsible for importation/batch

				release for captioned product
IMATINIB/MYLAN TABLET, FILM COATED 100MG	3646/19T	023472	MYLAN S.A.S.	B.I.a).2. e) Minor change to the restricted part of an Active Substance Master File To update the ASMF of PHARMACEUTICAL RESEARCH INSTITUTE (PRI) to version: Applicant's Part: ASMF/DOR/036-AP Ed. 02, April 2015 corr. 14.09.2018 Restricted Part: ASMF/BP/036-RP Ed. 02, April 2015 corr. 14.09.201
VALSIMIA TABLET, FILM COATED 10MG/160MG	3403/19T	022441	ELPEN PHARMACEUTICAL CO INC	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VALSIMIA TABLET, FILM COATED 5MG/160MG	3402/19T	022440	ELPEN PHARMACEUTICAL CO INC	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VALSIMIA TABLET, FILM COATED 5MG/80MG	3401/19T	022439	ELPEN PHARMACEUTICAL CO INC	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
IMATINIB/MYLAN TABLET, FILM COATED 100MG	2140/19T	023472	MYLAN S.A.S.	B.I.b).2. e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate To change the analytical method (replacement of method) of the finished product manufacturer (Remedica) for the

				determination of the following genotoxic impurities: - 4-(Chloromethyl)-N-(4-methyl-3-{[4-(pyridin-3-yl) pyrimidin-2-yl] amino} phenyl) benzamide (Imatinib IM-6) and - Sum of 4-(Chloromethyl) benzoic acid (ChMBA) and 4-(Chloromethyl) benzoyl chloride (ChMBCl) in Imatinib Mesylate API received from Pharmaceutical Research Institute (PRI). Formerly, the finished product manufacturer (Remedica) adopted the analytical methods described in Pharmaceutical Research Institute's (PRI) ASMF for these genotoxic impurities
IMATINIB/MYLAN TABLET, FILM COATED 100MG	2271/19T	023472	MYLAN S.A.S.	B.I.a).3. a) Up to 10-fold increase compared to the originally approved batch size increase of the batch size of the active substance up to 10-fold, from 13.50 kg - 15.75 kg to 45.00 kg - 55.00 kg. All conditions of the variations guideline for the scale up (B.I.a.3.a - Type IA) are fulfilled.
IMATINIB/MYLAN TABLET, FILM COATED 100MG	2006/19T	023472	MYLAN S.A.S.	B.II.d).1. a) Tightening of specification limits to tighten the shelf-life specification limit of total impurities from NMT 1.6% to NMT 1.2%.
IMATINIB/MYLAN TABLET, FILM COATED 400MG	1299/19T	023473	MYLAN S.A.S.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH

IMATINIB/MYLAN TABLET, FILM COATED 100MG	1298/19T	023472	MYLAN S.A.S.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH-Withdrawn of MA (withdrawn date-17/01/2023)
IMATINIB/MYLAN TABLET, FILM COATED 100MG	1013/19T	023472	MYLAN S.A.S.	A.2. b) for Nationally Authorised Products In France Only. Change the name of the medicinal product form IMATINIB MYLAN 100 mg,400 mg comprimé pelliculé to. IMATINIB MYLAN 100 mg,400 mg comprimé pelliculé sécable
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.3MG/ML	478/19T	022780	PHARMATHEN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH By means of this variation, we would like to update the Product Information Texts of procedure DK/H/2495/001-002/DC, in accordance to the centrally approved reference product Lumigan.
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.1MG/ML	477/19T	022779	PHARMATHEN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH By means of this variation, we would like to update the Product Information Texts of procedure DK/H/2495/001-002/DC, in accordance to the centrally approved reference product Lumigan.
YODAFAR TABLET 300MCG	83012-83015/18T	021718	BIAL-PORTELA & CA, SA	B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site

				B.II.b).2.c). 2 Including batch control/testing B.III.1.a). 2 Updated certificate from an already approved manufacturer
YODAFAR TABLET 200MCG	8308-83011/18T	021717	BIAL-PORTELA & CA, SA	B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site B.II.b).2.c). 2 Including batch control/testing B.III.1.a). 2 Updated certificate from an already approved manufacturer
LAMIVUDINE/ZIDOVUDINE ACCORD TABLET, FILM COATED 150MG/300MG	8008/18T	023309	ACCORD HEALTHCARE LIMITED	C.I. z) Other variation C.I.z. - to propose amendments in the product information in-line with the PRAC signal recommendation for Lamivudine/Zidovudine 150/300 mg Film coated tablets.
RIDOCA CAPSULE, HARD 100MG	1657-1661/18T	022132	AENORASIS SA	B.III.1.b). 2 New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer B.III.1.b). 4 Deletion of certificates (in case multiple certificates exist per material) B.III.1.b). 2 - Introduction of additional TSE Certificate of suitability for Gelatin: Rousselot R1-CEP 2010-043-Rev 00. B.III.1.b). 4 - Deletion of four obsolete TSE Certificates of suitability for Gelatin: Gelita Group R1-CEP 2003-172-Rev 01, Rousselot R1-CEP 2000-027-Rev 02, Rousselot R1-CEP

				2001-332-Rev 02, PB Gelatins R1-CEP 2002-110-Rev 00
MAVIXAN TABLET 10MG	6493/18T	021314	PHARMATHEN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH Adaptation of the SPC and PIL to reference product MAXALT (NL/H/0144), to the current QRD template (incl. implementation of the safety features on the packaging, section 17 and 18 [Doc. Ref: CMDh/345/2016; February 2016]) and to the excipients guideline
PHYSIONEAL 40 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86%	3922-3925/18T	022314	BAXTER (HELLAS) EPE	B.II.e).1.b). 3 Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form B.II.e).4. c) Sterile medicinal products B.II.e).6. b) Change that does not affect the product information B.III.2.z). Other variation B.III.2.z:The reference to the current version of Ph. Eur. monograph 3.1.6 for inner and outer layers of the primary film is introduced with this variation. B.II.e.4.c:The Master batch is no longer used for the

				production of the inner layer of the primary film, therefore a deletion of the “Master batch” is proposed. BII.e.6.b: Due to initial production issues with the peelable film (top layer of 95 µm), the content of Polyamide has been increased, which resulted in increased thickness of top layer (106 µm). B.II.e.1.b.3: The Lineo connector is included in the currently approved dossier as an alternate connector for CAPD bags. This type of connector is no longer used, and is not planned to be used in the future.
PHYSIONEAL 40 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	3918-3921/18T	022313	BAXTER (HELLAS) EPE	B.II.e).1.b). 3 Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form B.II.e).4. c) Sterile medicinal products B.II.e).6. b) Change that does not affect the product information B.III.2.z). Other variation B.III.2.z:The reference to the current version of Ph. Eur. monograph 3.1.6 for inner and outer layers of the primary film is introduced with this variation. B.II.e.4.c:The Master batch is no longer used for the production of the inner layer of the primary film, therefore a deletion of the “Master batch” is proposed.

				BII.e.6.b: Due to initial production issues with the peelable film (top layer of 95 µm), the content of Polyamide has been increased, which resulted in increased thickness of top layer (106 µm). B.II.e.1.b.3: The Lineo connector is included in the currently approved dossier as an alternate connector for CAPD bags. This type of connector is no longer used, and is not planned to be used in the future.
PHYSIONEAL 40 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	3914-3917/18T	022312	BAXTER (HELLAS) EPE	B.II.e).1.b). 3 Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form B.II.e).4. c) Sterile medicinal products B.II.e).6. b) Change that does not affect the product information B.III.2.z). Other variation B.III.2.z:The reference to the current version of Ph. Eur. monograph 3.1.6 for inner and outer layers of the primary film is introduced with this variation. B.II.e.4.c:The Master batch is no longer used for the production of the inner layer of the primary film, therefore a deletion of the “Master batch” is proposed. BII.e.6.b: Due to initial production issues with the peelable film (top layer of 95 µm), the content of

				Polyamide has been increased, which resulted in increased thickness of top layer (106 µm). B.II.e.1.b.3: The Lineo connector is included in the currently approved dossier as an alternate connector for CAPD bags. This type of connector is no longer used, and is not planned to be used in the future.
PHYSIONEAL 35 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86% W/V	3910-3913/18T	022311	BAXTER (HELLAS) EPE	B.II.e).1.b). 3 Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form B.II.e).4. c) Sterile medicinal products B.II.e).6. b) Change that does not affect the product information B.III.2.z). Other variation B.III.2.z:The reference to the current version of Ph. Eur. monograph 3.1.6 for inner and outer layers of the primary film is introduced with this variation. B.II.e.4.c:The Master batch is no longer used for the production of the inner layer of the primary film, therefore a deletion of the “Master batch” is proposed. BII.e.6.b: Due to initial production issues with the peelable film (top layer of 95 µm), the content of Polyamide has been increased, which resulted in increased thickness of top layer (106 µm).

				B.II.e.1.b.3: The Lineo connector is included in the currently approved dossier as an alternate connector for CAPD bags. This type of connector is no longer used, and is not planned to be used in the future.
PHYSIONEAL 35 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	3906-3909/18T	022310	BAXTER (HELLAS) EPE	B.II.e).1.b). 3 Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form B.II.e).4. c) Sterile medicinal products B.II.e).6. b) Change that does not affect the product information B.III.2.z). Other variation B.III.2.z:The reference to the current version of Ph. Eur. monograph 3.1.6 for inner and outer layers of the primary film is introduced with this variation. B.II.e.4.c:The Master batch is no longer used for the production of the inner layer of the primary film, therefore a deletion of the “Master batch” is proposed. BII.e.6.b: Due to initial production issues with the peelable film (top layer of 95 µm), the content of Polyamide has been increased, which resulted in increased thickness of top layer (106 µm).

				B.II.e.1.b.3: The Lineo connector is included in the currently approved dossier as an alternate connector for CAPD bags. This type of connector is no longer used, and is not planned to be used in the future.
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	3760-3761/18T	023563	AUROBINDO PHARMA (MALTA) LIMITED	A.5. b) The activities for which the manufacturer/importer is responsible do not include batch release B.II.b).1. a) Secondary packaging site A.5. b) - Change in the name of the district and state of the finished product manufacturer i.e. Aurobindo Pharma Limited Unit III of Topiramate Aurobindo 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets. B.II.b).1. a) - Replacement of Segetra Pharma S.R.L., Italy with “DHL Supply Chain (Italy) SPA, Italy” as secondary packaging site.
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.3MG/ML	2722/18T	022780	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products Name change of the medicinal product in the CMS ES
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.1MG/ML	2721/18T	022779	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products Name change of the medicinal product in the CMS ES

MENTIFAR TABLET, FILM COATED 10MG	2458/18T	022204	RAFARM S.A.	B.I.a).1. b) Introduction of a manufacturer of the active substance supported by an ASMF B.I.a.1.b. - to include Hikal Limited as an additional source for Memantine Hydrochloride drug substance for use in the manufacture of Memantine tablets.
RIDOCA CAPSULE, HARD 250MG	1672-1676/18T	022135	AENORASIS SA	B.III.1.b). 2 New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer B.III.1.b). 4 Deletion of certificates (in case multiple certificates exist per material) B.III.1.b). 2 - Introduction of additional TSE Certificate of suitability for Gelatin: Rousselot R1-CEP 2010-043-Rev 00. B.III.1.b). 4 - Deletion of four obsolete TSE Certificates of suitability for Gelatin: Gelita Group R1-CEP 2003-172-Rev 01, Rousselot R1-CEP 2000-027-Rev 02, Rousselot R1-CEP 2001-332-Rev 02, PB Gelatins R1-CEP 2002-110-Rev 00
RIDOCA CAPSULE, HARD 180MG	1667-1671/18T	022134	AENORASIS SA	B.III.1.b). 2 New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer B.III.1.b). 4 Deletion of certificates (in case multiple certificates exist per

				material) B.III.1.b). 2 - Introduction of additional TSE Certificate of suitability for Gelatin: Rousselot R1-CEP 2010-043-Rev 00. B.III.1.b). 4 - Deletion of four obsolete TSE Certificates of suitability for Gelatin: Gelita Group R1-CEP 2003-172-Rev 01, Rousselot R1-CEP 2000-027-Rev 02, Rousselot R1-CEP 2001-332-Rev 02, PB Gelatins R1-CEP 2002-110-Rev 00
RIDOCA CAPSULE, HARD 140MG	1662-1666/18T	022133	AENORASIS SA	B.III.1.b). 2 New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer B.III.1.b). 4 Deletion of certificates (in case multiple certificates exist per material) B.III.1.b). 2 - Introduction of additional TSE Certificate of suitability for Gelatin: Rousselot R1-CEP 2010-043-Rev 00. B.III.1.b). 4 - Deletion of four obsolete TSE Certificates of suitability for Gelatin: Gelita Group R1-CEP 2003-172-Rev 01, Rousselot R1-CEP 2000-027-Rev 02, Rousselot R1-CEP 2001-332-Rev 02, PB Gelatins R1-CEP 2002-110-Rev 00

RIDOCA CAPSULE, HARD 20MG	1652-1656/18T	022131	AENORASIS SA	B.III.1.b). 2 New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer B.III.1.b). 4 Deletion of certificates (in case multiple certificates exist per material) B.III.1.b). 2 - Introduction of additional TSE Certificate of suitability for Gelatin: Rousselot R1-CEP 2010-043-Rev 00. B.III.1.b). 4 - Deletion of four obsolete TSE Certificates of suitability for Gelatin: Gelita Group R1-CEP 2003-172-Rev 01, Rousselot R1-CEP 2000-027-Rev 02, Rousselot R1-CEP 2001-332-Rev 02, PB Gelatins R1-CEP 2002-110-Rev 00
RIDOCA CAPSULE, HARD 5MG	1647-1651/18T	022130	AENORASIS SA	B.III.1.b). 2 New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer B.III.1.b). 4 Deletion of certificates (in case multiple certificates exist per material) B.III.1.b). 2 - Introduction of additional TSE Certificate of suitability for Gelatin: Rousselot R1-CEP 2010-043-Rev 00. B.III.1.b). 4 - Deletion of four obsolete TSE Certificates of suitability for

				Gelatin: Gelita Group R1-CEP 2003-172-Rev 01, Rousselot R1-CEP 2000-027-Rev 02, Rousselot R1-CEP 2001-332-Rev 02, PB Gelatins R1-CEP 2002-110-Rev 00
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	9518/17T	023566	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3. a) Implementation of wording agreed by the competent authority to update Summary of Product Characteristics and Package leaflet for Topiramate Aurobindo 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets with reference to PSUSA/00002996/ 201701 procedure.
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	9517/17T	023565	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3. a) Implementation of wording agreed by the competent authority to update Summary of Product Characteristics and Package leaflet for Topiramate Aurobindo 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets with reference to PSUSA/00002996/ 201701 procedure.
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	9516/17T	023564	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3. a) Implementation of wording agreed by the competent authority to update Summary of Product Characteristics and Package leaflet for Topiramate Aurobindo 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets with reference to PSUSA/00002996/ 201701 procedure.
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	9515/17T	023563	AUROBINDO PHARMA (MALTA) LIMITED	C.I.3. a) Implementation of wording agreed by the competent authority

				to update Summary of Product Characteristics and Package leaflet for Topiramate Aurobindo 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets with reference to PSUSA/00002996/ 201701 procedure.
SEVELAMER CARBONATE SANDOZ TABLET, FILM COATED 800MG	947117T	022154	SANDOZ GMBH	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH Based upon the most recent centrally approved Innovator (Genzyme B.V.) SmPC for Renvela: EMEA/H/C/993/WS /965 Dated 26 June2017, we herewith would like to update our SmPC and PL for Sevelamer. Herewith we state that both SmPC and PL are adapted identically to the reference text as foreseen in the respective variation.
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	7668/17T	023566	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.a, Type IB variation procedure to bring the product information of Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets in line with the product information of reference medicinal product i.e., Topamax 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets. Innovator

				procedure SE/H/0110
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	7667/17T	023565	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.a, Type IB variation procedure to bring the product information of Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets in line with the product information of reference medicinal product i.e., Topamax 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets. Innovator procedure SE/H/0110
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	7666/17T	023564	AUROBINDO PHARMA (MALTA) LIMITED	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.2.a, Type IB variation procedure to bring the product information of Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets in line with the product information of reference medicinal product i.e., Topamax 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets. Innovator procedure SE/H/0110
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.3MG/ML	7390/17T	022780	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products A.2: Change in the (invented) name of the medicinal product

				b): for Nationally Authorised Products - Change in the name of the medicinal product in the CMS (UK) only from "Bimatoprost Pharmathen " to "Bimatoprost Aspire", due to MAH transfer from Pharmathen S.A to Aspire Pharma Limited .
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.1MG/ML	7389/17T	022779	PHARMATHEN S.A.	A.2. b) for Nationally Authorised Products A.2: Change in the (invented) name of the medicinal product b): for Nationally Authorised Products - Change in the name of the medicinal product in the CMS (UK) only from "Bimatoprost Pharmathen " to "Bimatoprost Aspire", due to MAH transfer from Pharmathen S.A to Aspire Pharma Limited .
MEDOTIS TABLET, GASTRO-RESISTANT 20MG	7158/17T	021394	ZENTIVA K.S.	C.I.3. z) Other variation To update section 4.8 of the SPC by adding microscopic colitis as an undesirable effect with frequency unknown following the outcome of PSUSA/00002601/201610 for Rabeprazole. Consequently the patient information leaflet has been updated. Additionally, the labelling has also been updated in line with the latest QRD template.

ACTONEL OAW TABLET, FILM COATED 35MG	6565/17T	019723	INNOVIS PHARMA S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location The applicant applies for the change of the PSMF summary from Actavis to Teva (the Teva-PSMF is applicable for all Teva group companies in Europe, see annex to this application form). The PSMF summary is attached in Module 1.8.1 of this application.
RIDOCA CAPSULE, HARD 250MG	4130-4132/17T	022135	AENORASIS SA	B.I.a).2. e) Minor change to the restricted part of an Active Substance Master File B.I.b).2. a) Minor changes to an approved test procedure B.III.2.a). 1 Active substance Submission of an update of an ASMF for Temozolomide from Active substance manufacturer Perrigo API LTD, Israel Version 6.0 (2016-12-13). The following variations are part of this variation: n-heptane was removed from the method TEMO-21 for residual solvents. n-Heptane is used in early stages of the process, and was temporary monitored with this method. It is not part of the specification (3.2.S.4.1) of the

				API Recently the Ph. Eur. monograph of Temozolomide became valid. The ASMF V6.0 has been aligned to the new monograph. The sections 3.2.S.1.1., 3.2.S.4.1., 3.2.S.4.4. and 3.2.S.4.5. were revised. The comparison report for Perrigo API´s in-house methods versus the Ph. Eur. methods has been added to 3.2.S.4.3. .
RIDOCA CAPSULE, HARD 180MG	4127-4129/17T	022134	AENORASIS SA	B.I.a).2. e) Minor change to the restricted part of an Active Substance Master File B.I.b).2. a) Minor changes to an approved test procedure B.III.2.a). 1 Active substance Submission of an update of an ASMF for Temozolomide from Active substance manufacturer Perrigo API LTD, Israel Version 6.0 (2016-12-13). The following variations are part of this variation: n-heptane was removed from the method TEMO-21 for residual solvents. n-Heptane is used in early stages of the process, and was temporary monitored with this method. It is not part of the specification (3.2.S.4.1) of the API Recently the Ph. Eur. monograph of Temozolomide became valid. The ASMF V6.0 has been aligned to the new monograph. The sections

				3.2.S.1.1., 3.2.S.4.1., 3.2.S.4.4. and 3.2.S.4.5. were revised. The comparison report for Perrigo API´s in-house methods versus the Ph. Eur. methods has been added to 3.2.S.4.3. .
RIDOCA CAPSULE, HARD 140MG	4124-4126/17T	022133	AENORASIS SA	B.I.a).2. e) Minor change to the restricted part of an Active Substance Master File B.I.b).2. a) Minor changes to an approved test procedure B.III.2.a). 1 Active substance Submission of an update of an ASMF for Temozolomide from Active substance manufacturer Perrigo API LTD, Israel Version 6.0 (2016-12-13). The following variations are part of this variation: n-heptane was removed from the method TEMO-21 for residual solvents. n-Heptane is used in early stages of the process, and was temporary monitored with this method. It is not part of the specification (3.2.S.4.1) of the API Recently the Ph. Eur. monograph of Temozolomide became valid. The ASMF V6.0 has been aligned to the new monograph. The sections 3.2.S.1.1., 3.2.S.4.1., 3.2.S.4.4. and 3.2.S.4.5. were revised. The

				comparison report for Perrigo API´s in-house methods versus the Ph. Eur. methods has been added to 3.2.S.4.3. .
RIDOCA CAPSULE, HARD 100MG	4121-4123/17T	022132	AENORASIS SA	B.I.a).2. e) Minor change to the restricted part of an Active Substance Master File
RIDOCA CAPSULE, HARD 20MG	4118-4120/17T	022131	AENORASIS SA	B.I.b).2. a) Minor changes to an approved test procedure
RIDOCA CAPSULE, HARD 5MG	4115-4117/17T	022130	AENORASIS SA	B.III.2.a). 1 Active substance
MEDOTIS TABLET, GASTRO-RESISTANT 20MG	2046/17T	021394	ZENTIVA K.S.	C.I. z) Other variation To update SPC fragment 4.8 in line with the PRAC recommendation (EMA/PRAC/740369/2016, published on 3rd January 2017) for Rabeprazole. Consequential change have been made to the PIL.
IMATINIB/MYLAN TABLET, FILM COATED 100MG	1320/17T	023472	MYLAN PHARMACEUTICALS LIMITED	Submission of an update of an ASMF for Temozolomide from Active substance manufacturer Perrigo API LTD, Israel Version 6.0 (2016-12-13). The following variations are part of this variation:
PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 4MMOL/L	692-698/17T	021045	GAMBRO LUNDIA AB	n-heptane was removed from the method TEMO-21 for residual solvents. n-Heptane is used in early stages of the process, and was temporary monitored with this method. It is not part of the specification (3.2.S.4.1) of the API

PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 2MMOL/L	685-691/17T	021044	GAMBRO LUNDIA AB	Recently the Ph. Eur. monograph of Temozolomide became valid. The ASMF V6.0 has been aligned to the new monograph. The sections 3.2.S.1.1., 3.2.S.4.1., 3.2.S.4.4. and 3.2.S.4.5. were revised. The comparison report for Perrigo API´s in-house methods versus the Ph. Eur. methods has been added to 3.2.S.4.3. .
BETAHISTINE AUROBINDO TABLET 8MG	8822-23/16T	023303	AUROBINDO PHARMA (MALTA) LIMITED	B.II.e).5.a). 1 Change within the range of the currently approved pack sizes To add a new blister pack size i.e., 30s.
THEROFLAN TABLET 0.5MG	4832/16T	020713	PHARMATHEN S.A.	A.1. Change in the name and/or address of the marketing authorisation holder To register a change in the address of the marketing authorisation holder S.F. Group S.R.L. for Italy only. The current S.F. Group S.R.L., Via Beniamino Segre, 59, 00134 - Roma (RM), Italia will be superseded by the proposed S.F. Group S.R.L., Via Tiburtina, 1143, 00156 - Roma (RM), Italia.
THEROFLAN TABLET 0.5MG	9681/15T	020713	PHARMATHEN S.A.	C.I.8. a) Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location To register an update to the PSMF summary following the MA transfer in Italy from

				Pharmacare S.r.l. to SF GROUP Srl:
THEROFLAN TABLET 0.5MG	6659/14T, 6662/14T	020713	PHARMATHEN S.A.	B.III.1.a). 1 New certificate from an already approved manufacturer B.III.1.a). 2 Updated certificate from an already approved manufacturer 1) To replace DMF with EDQM Certificate of Suitability R0-CEP 2008-093-Rev 00, for the active substance Repaglinide, manufactured by Biocon Limited, 20th KM Hosur Road, Electronics City, India – 560 100 Bangalore, Karnataka. The certificate supports a conditional retest period of 3 years. 2) To register an updated EDQM Certificate of Suitability, R1-CEP 2008-044-Rev 01, (replacing previous certificate R0-CEP 2008-044-Rev 00), for the active substance Repaglinide, manufactured by Aurobindo Pharma Limited, Unit –XI, Survey No. 61-66, I.D.A. Srikakulam District, Ranasthalam Mandal, India – 532 409 Pydibhimavaram Village, Andhra Pradesh.
THEROFLAN TABLET 0.5MG	8125/11T	020713	PHARMATHEN S.A.	B.II.b).4. a) Up to 10-fold compared to the currently approved batch size To add a batch size range of 100,000 tablets to 750,000 for Theroflan 0.5 mg, 1.0 mg and 2.0 mg tablets.

THEROFLAN TABLET 0.5MG	8073,8076,8079,8082,8085,8088,8091,8094,8097/11T	020713	PHARMATHEN S.A.	C.I.9. a) Change in the QPPV C.I.9. b) Change in the contact details of the QPPV C.I.9. d) Change in the safety database (e.g. Introduction of a new safety database including transfer of safety data collection and/or analysis and reporting to the new system) C.I.9. h) Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system (e.g. change of the major storage/archiving location, administrative changes, update of acronyms, naming changes of functions/procedures). C.I.9. i) Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH. The DDPS version is updated to version 4.01 from the previous version 3.03. 1. To register a change in the QPPV, the new QPPV is Dimitrios Antoniadis, Address: PHARMATHEN S.A., 6, Dervenakion str., 153 51, Pallini, Attiki, Greece; Telephone: (+30) 210 6604300 ext. 493; Mobile Phone: (+30) 210 6604300 ext. 9; Email: dantoniadis@pharmathen.com 2. To register a change in the back-up procedure of the QPPV, the deputy QPPV is Evangelia

				Dova, Address: PHARMATHEN S.A., 6, Dervenakion str., 153 51, Pallini, Attiki, Greece; Tel.: (+30) 210 6604300 ext. 423; Fax: (+30) 210 6604583; Email: edova@pharmathen.com 3. To register changes in the safety database. 4. To register other changes to the DDPS that does not imapct on the operation of the Pharmacovigilance system. 5. To register changes to an existing pharmacovigilance system as described in the DDPS, specifically changes to the DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
THEROFLAN TABLET 0.5MG	4286,4289,4292/11T	020713	PHARMATHEN S.A.	B.I.b).1. f) Change outside the approved specifications limits range for the active substance To change the limits for the particle size distribution parameter for the active substance manufactured by Aurobindo.
THEROFLAN TABLET 0.5MG	4286,4289,4292/11T		PHARMATHEN S.A.	B.I.b).1. c) Addition of a new specification parameter to the specification with its corresponding test method B.III.1.a). 3 New certificate from a new manufacturer (replacement or addition) To add Aurobindo Pharma Limited (Unit-XI, Survey No 61-66, I.D.A. Srikakulam District,

				Ranasthalam Mandal, India-532 409, Pydibhumavaram Village, Andhra Pradesh) as an active substance manufacturer supported by CEP R0-CEP 2008-044-Rev 00. To additionally add a parameter for Melting Range to the active substance specification from Aurobindo, with limits of 132 deg C to 136 deg C.
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	3762-3763/18T	23564	AUROBINDO PHARMA (MALTA) LIMITED	A.5. b) The activities for which the manufacturer/importer is responsible do not include batch release B.II.b).1. a) Secondary packaging site A.5. b) - Change in the name of the district and state of the finished product manufacturer i.e. Aurobindo Pharma Limited Unit III of Topiramate Aurobindo 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets. B.II.b).1. a) - Replacement of Segetra Pharma S.R.L., Italy with “DHL Supply Chain (Italy) SPA, Italy” as secondary packaging site.
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	3764-3765/18T	023565	AUROBINDO PHARMA (MALTA) LIMITED	A.5. b) The activities for which the manufacturer/importer is responsible do not include batch release B.II.b).1. a) Secondary packaging site A.5. b) - Change in the name of the district and state of the finished product manufacturer i.e.

				Aurobindo Pharma Limited Unit III of Topiramate Aurobindo 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets. B.II.b).1. a) - Replacement of Segetra Pharma S.R.L., Italy with “DHL Supply Chain (Italy) SPA, Italy” as secondary packaging site.
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	3766-3767/18T	23566	AUROBINDO PHARMA (MALTA) LIMITED	A.5. b) The activities for which the manufacturer/importer is responsible do not include batch release B.II.b).1. a) Secondary packaging site A.5. b) - Change in the name of the district and state of the finished product manufacturer i.e. Aurobindo Pharma Limited Unit III of Topiramate Aurobindo 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets. B.II.b).1. a) - Replacement of Segetra Pharma S.R.L., Italy with “DHL Supply Chain (Italy) SPA, Italy” as secondary packaging site.
MAVIXAN TABLET 5MG	6492/18T	021313PHARMATHEN S.A.		C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH Adaptation of the SPC and PIL to reference product MAXALT (NL/H/0144), to the current QRD template (incl. implementation of the safety features on the packaging, section 17 and 18 [Doc. Ref: CMDh/345/2016; February 2016]) and to the excipients guideline

MENTIFAR TABLET, FILM COATED 20MG	2459/18T	22205	RAFARM S.A.	B.I.a).1. b) Introduction of a manufacturer of the active substance supported by an ASMF B.I.a.1.b. - to include Hikal Limited as an additional source for Memantine Hydrochloride drug substance for use in the manufacture of Memantine tablets.
MEDOTIS TABLET, GASTRO-RESISTANT 10MG	7157/17T	21393	ZENTIVA K.S.	C.I.3. z) Other variation To update section 4.8 of the SPC by adding microscopic colitis as an undesirable effect with frequency unknown following the outcome of PSUSA/00002601/ 201610 for Rabeprazole. Consequently the patient information leaflet has been updated. Additionally, the labelling has also been updated in line with the latest QRD template.
MEDOTIS TABLET, GASTRO-RESISTANT 10MG	2045/17T	21393	ZENTIVA K.S.	C.I.3. z) Other variation To update section 4.8 of the SPC by adding microscopic colitis as an undesirable effect with frequency unknown following the outcome of PSUSA/00002601/ 201610 for Rabeprazole. Consequently the patient information leaflet has been updated. Additionally, the labelling has also been updated in line with the latest QRD template.
IMATINIB/MYLAN TABLET, FILM COATED 400MG	1014/19T	23473	MYLAN PHARMACEUTICALS LIMITED	A.2. b) for Nationally Authorised Products In France Only. Change the name of the medicinal product

				form IMATINIB MYLAN 100 mg,400 mg comprimé pelliculé to. IMATINIB MYLAN 100 mg,400 mg comprimé pelliculé sécable
IMATINIB/MYLAN TABLET, FILM COATED 400MG	2141/19T	23473	MYLAN PHARMACEUTICALS LIMITED	B.I.b).2. e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate To change the analytical method (replacement of method) of the finished product manufacturer (Remedica) for the determination of the following genotoxic impurities: - 4-(Chloromethyl)-N-(4-methyl-3-{[4-(pyridin-3-yl) pyrimidin-2-yl] amino} phenyl) benzamide (Imatinib IM-6) and - Sum of 4-(Chloromethyl) benzoic acid (ChMBA) and 4-(Chloromethyl) benzoyl chloride (ChMBCl) in Imatinib Mesylate API received from Pharmaceutical Research Institute (PRI). Formerly, the finished product manufacturer (Remedica) adopted the analytical methods described in Pharmaceutical Research Institute's (PRI) ASMF for these genotoxic impurities.
IMATINIB/MYLAN TABLET, FILM COATED 400MG	2272/19T	23473	MYLAN PHARMACEUTICALS LIMITED	B.I.a).3. a) Up to 10-fold increase compared to the originally approved batch size increase of the

				batch size of the active substance up to 10-fold, from 13.50 kg - 15.75 kg to 45.00 kg - 55.00 kg. All conditions of the variations guideline for the scale up (B.I.a.3.a - Type IA) are fulfilled.
IMATINIB/MYLAN TABLET, FILM COATED 400MG	2007/19T	23473	MYLAN PHARMACEUTICALS LIMITED	B.II.d).1. a) Tightening of specification limits to tighten the shelf-life specification limit of total impurities from NMT 1.6% to NMT 1.2%.
IMATINIB/MYLAN TABLET, FILM COATED 400MG	3647/19T	23473	MYLAN PHARMACEUTICALS LIMITED	B.I.a).2. e) Minor change to the restricted part of an Active Substance Master File To update the ASMF of PHARMACEUTICAL RESEARCH INSTITUTE (PRI) to version: Applicant's Part: ASMF/DOR/036-AP Ed. 02, April 2015 corr. 14.09.2018 Restricted Part: ASMF/BP/036-RP Ed. 02, April 2015 corr. 14.09.201

ADONIS CHRISTOFI

Τυπώθηκε στο Τυπογραφείο της Κυπριακής Δημοκρατίας, 1445 Λευκωσία, Κύπρος
Τηλ. 22405824, Φαξ 22303175 – www.mof.gov.cy/gpo
Αντίτυπα της Επίσημης Εφημερίδας πωλούνται προς €2,00 το καθένα