ΕΠΙΣΗΜΗ ΕΦΗΜΕΡΙΔΑ

ΤΗΣ ΚΥΠΡΙΑΚΗΣ ΔΗΜΟΚΡΑΤΙΑΣ

ΚΥΡΙΟ ΜΕΡΟΣ

ΤΜΗΜΑ Β

Αριθμός 5445	Παρασκευή, 11 Αυγούστου 2023	6409

Αριθμός 4276

ΑΝΑΝΕΩΣΕΙΣ ΠΑΡΑΛΛΗΛΗΣ ΕΙΣΑΓΩΓΗΣ ΠΟΥ ΕΧΟΥΝ ΕΓΚΡΙΘΕΙ 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:

Όνομα Φαρμακευτικού Προϊόντος	Αρ. Άδειας Παράλληλης Εισαγωγής	Κάτοχος Άδειας Παράλληλης Εισαγωγής	Ημερομηνίας Τελευταίας Ανανέωσης
ATROVENT SOLUTION FOR INHALATION 500MCG/2ML	PI0068	PHARMAFAST LTD	21/06/2023
OMNIC TOCAS TABLET, PROLONGED-RELEASE 0.4MG	PI0055	PHARMAFAST LTD	21/06/2023
REGAINE CUTANEOUS SOLUTION 5% W/V	PI0070	KRINERA HEALTH LTD	21/06/2023
TRAVOCORT CREAM	PI0041	KRINERA HEALTH LTD	21/06/2023
TRAVOCORT CREAM (1%+0.1%)		PHARMAFAST LTD	21/06/2023

Αριθμός 4277

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: 053
   Ημερομηνία Έκδοσης Άδειας: 23/05/2018
   Προηγούμενη λήξη: 22/05/2023
   Ισχύει μέχρι: 22/05/2028
   Κάτοχος Άδειας: M.A. PHARMACEUTICALS TRADING LTD
   Διεύθυνση Αλληλογραφίας: Τ.Θ.50222, 3602 Λεμεσός, Κύπρος

Το πεδίο εφαρμογής της πιο πάνω Άδειας είναι: Εργασίες Μερικής Παρασκευής (Δευτερογενής Συσκευασία)
Εισαγωγή φαρμακευτικών προϊόντων από τρίτες χώρες

2. Αριθμός Άδειας: 026
   Ημερομηνία Έκδοσης Άδειας: 30/6/2003
   Προηγούμενη λήξη: 29/6/2023
   Ισχύει μέχρι: 29/6/2028
   Κάτοχος Άδειας: MEDILINK PHARMACEUTICALS LTD
   Διεύθυνση Αλληλογραφίας: Τ.Κ. 26576, 1640, Λευκωσία

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

3. Αριθμός Άδειας: 051
   Ημερομηνία Έκδοσης Άδειας: 19/03/2018
   Προηγούμενη λήξη: 18/03/2023
   Ισχύει μέχρι: 18/03/2028
   Κάτοχος Άδειας: ACIC EUROPE LTD
   Διεύθυνση Αλληλογραφίας: Λεοντίου 163, κτήριο CLERIMOS, 2ος Όροφος, Λεμεσός 3022, Κύπρος

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

4. Αριθμός Άδειας: 025
   Ημερομηνία Έκδοσης Άδειας: 23/6/2003
   Προηγούμενη λήξη: 22/06/2023
   Ισχύει μέχρι: 22/06/2028
   Κάτοχος Άδειας: PHARMACYLINE C. A. PAPAELLINAS LTD
   Διεύθυνση Αλληλογραφίας: Τ:Θ. 24018, 1700, Λευκωσία

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

5. Αριθμός Άδειας: 028
   Ημερομηνία Έκδοσης Άδειας: 5/09/2003
   Προηγούμενη λήξη: 4/09/2023
   Ισχύει μέχρι: 4/09/2028
   Κάτοχος Άδειας: M. S. JACOVIDES & CO LTD
   Διεύθυνση Αλληλογραφίας: Αγίου Νικολάου 8, 1055 Λευκωσία

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

Αριθμός 4278

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: 010
   Ημερομηνία Έκδοσης Άδειας: 23/06/2003
   Προηγούμενη λήξη: 22/06/2023
   Ισχύει μέχρι: 22/06/2028
   Κάτοχος Άδειας: ΑΓΑΠΗΝΩΡ ΦΑΡΜΑΚΕΥΤΙΚΗ ΛΤΔ
   Διεύθυνση Αλληλογραφίας: 6 Aglaias street, Flat 41, Pallouriotissa, 1035, Nicosia, Cyprus

2. Αριθμός Άδειας: 092
   Ημερομηνία Έκδοσης Άδειας: 09/07/2013
   Προηγούμενη λήξη: 08/07/2023
   Ισχύει μέχρι: 08/07/2028
   Κάτοχος Άδειας: C.G.PAPALOISOU LTD
   Διεύθυνση Αλληλογραφίας: P.O. BOX 17112, Latsia, Nicosia, 2261, Cyprus

3. Αριθμός Άδειας: 017
   Ημερομηνία Έκδοσης Άδειας: 13/10/2003
   Προηγούμενη λήξη: 12/10/2023
   Ισχύει μέχρι: 12/10/2028
   Κάτοχος Άδειας: CYPRUS PHARMACEUTICAL ORGANISATION LTD
   Διεύθυνση Αλληλογραφίας: P.O.BOX 21005, 1500, Nicosia, Cyprus

4. Αριθμός Άδειας: 012
   Ημερομηνία Έκδοσης Άδειας: 04/07/2003
   Προηγούμενη λήξη: 03/07/2023
   Ισχύει μέχρι: 03/07/2028
   Κάτοχος Άδειας: C. A. PAPAELLINAS LTD
   Διεύθυνση Αλληλογραφίας: P.O. BOX 24018, NICOSIA, 1700, Cyprus

5. Αριθμός Άδειας: 094
   Ημερομηνία Έκδοσης Άδειας: 14/10/2013
   Προηγούμενη λήξη: 13/10/2023
   Ισχύει μέχρι: 13/10/2028
   Κάτοχος Άδειας: ALECTOR PHARMACEUTICALS LTD
   Διεύθυνση Αλληλογραφίας: P.O. BOX 17112, Latsia, Nicosia, 2261, Cyprus

Αριθμός 4279

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 υπέβαλε ο αιτητής, έχει εκδώσει την πιο κάτω νέα Άδεια Παρασκευής Καλλυντικών Προϊόντων με τα πιο κάτω στοιχεία:

1. Αριθμός Άδειας: 039
   Ημερομηνία Έκδοσης Άδειας: 2/5/2023
   Ισχύει μέχρι: 1/5/2028
   Κάτοχος Άδειας: VRAMAN PROPERTIES LTD
   Διεύθυνση Αλληλογραφίας: Τ.Θ.12115, 2341 Λακατάμεια, Λευκωσία.

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

Αριθμός 4280

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: 161
   Ημερομηνία Έκδοσης Άδειας: 30/01/2023
   Ισχύει μέχρι: 29/01/2028
   Κάτοχος Άδειας: DELORBIS PHARMACEUTICALS LTD
   Διεύθυνση Αλληλογραφίας: P.O. Box 28629, 2081, Lefkosia, Cyprus

2. Αριθμός Άδειας: 162
   Ημερομηνία Έκδοσης Άδειας: 30/01/2023
   Ισχύει μέχρι: 29/01/2028
   Κάτοχος Άδειας: D&FISHER CO LIMITED
   Διεύθυνση Αλληλογραφίας: 14 Lapithou street, Office 208A, 2410, Engomi, Nicosia

3. Αριθμός Άδειας: 163
   Ημερομηνία Έκδοσης Άδειας: 02/06/2023
   Ισχύει μέχρι: 01/06/2028
   Κάτοχος Άδειας: OMEGA ALPHARM (CYPRUS) LTD
   Διεύθυνση Αλληλογραφίας: 6 Kolokotronis Street, 1101, Nicosia, Cyprus

4. Αριθμός Άδειας: 164
   Ημερομηνία Έκδοσης Άδειας: 26/06/2023
   Ισχύει μέχρι: 25/06/2028
   Κάτοχος Άδειας: PHARMANEST TRADING LIMITED
   Διεύθυνση Αλληλογραφίας: 14 Lapithou Street, Office 007, Egkomi 2410, Nicosia, Cyprus

5. Αριθμός Άδειας: 165
   Ημερομηνία Έκδοσης Άδειας: 26/06/2023
   Ισχύει μέχρι: 25/06/2028
   Κάτοχος Άδειας: APUS PHARM LIMITED
   Διεύθυνση Αλληλογραφίας: 33 Vasilissis Frederikis, Palais D'Ivoire House, 2nd floor, 1066 Nicosia, Cyprus

6. Αριθμός Άδειας: 166
   Ημερομηνία Έκδοσης Άδειας: 26/06/2023
   Ισχύει μέχρι: 25/06/2028
   Κάτοχος Άδειας: DS PHARMA LIMITED
   Διεύθυνση Αλληλογραφίας: 37 Emmanouil Xanthou, Egkomi, 2415, Nicosia, Cyprus

7. Αριθμός Άδειας: 167
   Ημερομηνία Έκδοσης Άδειας: 26/06/2023
   Ισχύει μέχρι: 25/06/2028
   Κάτοχος Άδειας: MUNDIPHARMA PHARMACEUTICALS LTD
   Διεύθυνση Αλληλογραφίας: DHALI INDUSTRIAL AREA, OTHELLOU 13, P. O. BOX 23661, NICOSIA, 1685

Αριθμός 4281

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
41S0005	RESINSODIO POWDER FOR ORAL SUSPENSION 99.75G/100G	LABORATORIOS RUBIO, S.A.	24/05/2023
25S0010	MEDROL TABLET 16MG	PFIZER HELLAS AE	07/06/2023
24S0025	MEDROL TABLET 4MG	PFIZER HELLAS AE	07/06/2023
26S0388	EPANUTIN SOLUTION FOR INJECTION 50MG/ML	UPJOHN HELLAS LTD	08/03/2023
34S0035	POLYGYNAX VAGINAL CAPSULES	LABORATOIRE INNOTECH INTERNATIONAL	16/03/2023
36S0039	UNIMAZOLE TABLET 10MG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	22/02/2023
37S0006	CLINDAMYCIN ABR CAPSULE, HARD 300MG	ANTIBIOTIC-RAZGRAD AD	30/05/2023
24S0068	GASTROGRAFIN GASTROENTERAL SOLUTION	BAYER HELLAS ABEE	22/06/2023
24S0070	ANDROCUR TABLET 50MG	BAYER HELLAS ABEE	23/06/2023
41S0009	MODIWART CREAM 5% W/W	IASIS PHARMACEUTICALS HELLAS SA	01/06/2023
24S0026	XANAX TABLET 1MG	UPJOHN HELLAS LTD	07/06/2023
25S0002	KLYSMOL RECTAL SOLUTION	THE STAR MEDICINES IMPORTERS CO. LTD	16/06/2023
24S0074	CYCLACUR TABLET, COATED	BAYER HELLAS ABEE	23/06/2023
24S0008	NEZEFIB EYE DROPS, SOLUTION	RAFARM S.A.	07/06/2023
31S0032	CIPOCAL CREAM 0.005% W/W	PHARMEX S.A.	22/08/2023
31S0033	CIPOCAL OINTMENT 0.005% W/W	PHARMEX S.A.	22/08/2023
26S0299	FORTRANS POWDER FOR ORAL SOLUTION 74G	IPSEN CONSUMER HEALTHCARE	29/05/2023
41S0024	ORAMORPH ORAL SOLUTION 10MG/5ML	GLENWOOD GMBH	11/07/2023
33S0057	ENEMA COOPER ENEMA	COOPER PHARMACEUTICALS SA (COOPER S.A.)	08/07/2023
39S0014	IMURAN TABLET, FILM COATED 50MG	ASPEN PHARMA TRADING LIMITED	28/07/2023
41S0021	COLCHICINA/ACARPIA TABLET 1MG	ACARPIA FARMACEUTICI S.R.L	14/07/2023
33S0026	TRAVELGUM MEDICATED CHEWING-GUM 20MG	VIANEX S.A	09/07/2023
29S0083	CAVERJECT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 20MCG/VIAL	PFIZER HELLAS AE	01/12/2023

41S0034	BENDA-5 FU SOLUTION FOR INJECTION 50MG/ML	BENDALIS GMBH	09/09/2023
41S0037	OCTREOTID BENDALIS SOLUTION FOR INJECTION OR INFUSION 0.1MG/ML	BENDALIS GMBH	09/09/2023
37S0009	HEMAFER SYRUP 50MG/5ML	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	21/08/2023
29S0053	HEMAFER-S CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	25/08/2023
41S0023	LAMIVUDINE FARMOZ TABLET, FILM COATED 100MG	FARMOZ-SOCIEDADE TECNICO-MEDICINAL,S.A, PORTUGAL	11/07/2023
39S0007	DISTRANEURIN CAPSULE, SOFT 192MG	CHEPLAPHARM ARZNEIMITTEL GMBH.	21/07/2023
27S0165	PROTHURIL TABLET 50MG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	10/10/2023
37S0008	ALGOFRENELLE VAGINAL SOLUTION 1% W/V	IOULIA AND IRENE TSETI PHARMACEUTICAL LABORATORIES S.A.	21/08/2023
37S0007	THIOPENTAL VUAB POWDER FOR SOLUTION FOR INJECTION 1G/VIAL	VUAB PHARMA A.S.	23/08/2023
25S0040	POTASSIUM CHLORIDE/VIOSER SOLUTION FOR INJECTION 10%	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	10/08/2023
31S0041	MYCOMYCEN VAGINAL CREAM 1% W/W	VERISFIELD SINGLE MEMBER S.A.	24/08/2023
27S0129	ZAVEDOS POWDER FOR SOLUTION FOR INJECTION 5MG/VIAL	PFIZER HELLAS AE	11/10/2023
31S0055	DORALIN TABLET, FILM COATED 40MG	A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE SRL	25/08/2023
31S0043	IMIPENEM + CILASTATINA VENUS PHARMA POWDER FOR SOLUTION FOR INFUSION 500MG + 500MG	VENUS PHARMA GMBH	22/08/2023
31S0053	PAROTICIN EAR DROPS	ADELCO-CHROMATOURGIA ATHINON E.COLOCOTRONIS BROS S.A	23/08/2023
31S0052	ADEPRENAL ORAL DROPS SOLUTION 40MG/ML	ADELCO-CHROMATOURGIA ATHINON E.COLOCOTRONIS BROS S.A	23/08/2023
35S0015	FLECARDIA CAPSULE, HARD, PROLONGED-RELEASE 100MG	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	02/09/2023
35S0016	FLECARDIA CAPSULE, HARD, PROLONGED-RELEASE 200MG	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	02/09/2023
31S0040	MYCOMYCEN VAGINAL SUPPOSITORIES 100MG	VERISFIELD SINGLE MEMBER S.A.	22/09/2023

41S0022	FOSCAVIR SOLUTION FOR INFUSION 24MG/ML	CLINIGEN HEALTHCARE B.V.	09/09/2023
39S0032	ARTICLOX SOLUTION FOR INJECTION 1MG/2ML	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	02/12/2023
29S0059	STELAZINE MODIFIED-RELEASE CAPSULE, HARD 2MG	VIANEX S.A	17/09/2023
39S0001	THERACAP CAPSULE, HARD 37MBq to 5.55GBq	GE HEALTHCARE BUCHLER GMBH & CO KG	06/03/2023
29S0060	STELAZINE MODIFIED-RELEASE CAPSULE, HARD 10MG	VIANEX S.A	17/09/2023

Αριθμός 4282

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
PI0112	PLENDIL TABLET, PROLONGED-RELEASE 5MG	FELODIPINE 5. mg	ASTRAZENECA AB	18/01/2023
PI0112	PLENDIL TABLET, PROLONGED-RELEASE 5MG	FELODIPINE 5. mg	ASTRAZENECA GMBH	18/01/2023
PI0112	PLENDIL TABLET, PROLONGED-RELEASE 5MG	FELODIPINE 5. mg	KRINERA HEALTH LTD	18/01/2023
PI0112	PLENDIL TABLET, PROLONGED-RELEASE 5MG	FELODIPINE 5. mg	LIAFARM PHARMACEUTICALS SA	18/01/2023
PI0112	PLENDIL TABLET, PROLONGED-RELEASE 5MG	FELODIPINE 5. mg	MARVIFARM S.A.	18/01/2023
PI0112	PLENDIL TABLET, PROLONGED-RELEASE 5MG	FELODIPINE 5. mg	MEDICAMERC S.A PHARMACEUTICALS	18/01/2023
PI0112	PLENDIL TABLET, PROLONGED-RELEASE 5MG	FELODIPINE 5. mg	PHARMASERVICE SA	18/01/2023
PI0113	PLENDIL TABLET, PROLONGED-RELEASE 10MG	FELODIPINE 10. mg	ASTRAZENECA AB	18/01/2023
PI0113	PLENDIL TABLET, PROLONGED-RELEASE 10MG	FELODIPINE 10. mg	ASTRAZENECA GMBH	18/01/2023

PI0113	PLENDIL TABLET, PROLONGED-RELEASE 10MG	FELODIPINE 10. mg	KRINERA HEALTH LTD	18/01/2023
PI0113	PLENDIL TABLET, PROLONGED-RELEASE 10MG	FELODIPINE 10. mg	LIAFARM PHARMACEUTICALS SA	18/01/2023
PI0113	PLENDIL TABLET, PROLONGED-RELEASE 10MG	FELODIPINE 10. mg	MARVIFARM S.A.	18/01/2023
PI0113	PLENDIL TABLET, PROLONGED-RELEASE 10MG	FELODIPINE 10. mg	MEDICAMERC S.A PHARMACEUTICALS	18/01/2023
PI0113	PLENDIL TABLET, PROLONGED-RELEASE 10MG	FELODIPINE 10. mg	PHARMASERVICE SA	18/01/2023
PI0114	AUGMENTIN MF POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	AMOXICILLIN TRIHYDRATE 459.17 mg | CLAVULANATE POTASSIUM 67.9 mg	GLAXO WELLCOME PRODUCTION	29/03/2023
PI0114	AUGMENTIN MF POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	AMOXICILLIN TRIHYDRATE 459.17 mg | CLAVULANATE POTASSIUM 67.9 mg	KRINERA HEALTH LTD	29/03/2023
PI0114	AUGMENTIN MF POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	AMOXICILLIN TRIHYDRATE 459.17 mg | CLAVULANATE POTASSIUM 67.9 mg	LIAFARM PHARMACEUTICALS SA	29/03/2023
PI0114	AUGMENTIN MF POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	AMOXICILLIN TRIHYDRATE 459.17 mg | CLAVULANATE POTASSIUM 67.9 mg	MARVIFARM S.A.	29/03/2023
PI0114	AUGMENTIN MF POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	AMOXICILLIN TRIHYDRATE 459.17 mg | CLAVULANATE POTASSIUM 67.9 mg	MEDICAMERC S.A PHARMACEUTICALS	29/03/2023
PI0114	AUGMENTIN MF POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	AMOXICILLIN TRIHYDRATE 459.17 mg | CLAVULANATE POTASSIUM 67.9 mg	PHARMASERVICE SA	29/03/2023
PI0115	FUCIDIN CREAM 2%	FUCIDIC ACID 20. mg	KRINERA HEALTH LTD	29/03/2023
PI0115	FUCIDIN CREAM 2%	FUCIDIC ACID 20. mg	LEO LABORATORIES LTD	29/03/2023
PI0115	FUCIDIN CREAM 2%	FUCIDIC ACID 20. mg	LIAFARM PHARMACEUTICALS SA	29/03/2023
PI0115	FUCIDIN CREAM 2%	FUCIDIC ACID 20. mg	MARVIFARM S.A.	29/03/2023
PI0115	FUCIDIN CREAM 2%	FUCIDIC ACID 20. mg	MEDICAMERC S.A PHARMACEUTICALS	29/03/2023
PI0115	FUCIDIN CREAM 2%	FUCIDIC ACID 20. mg	PHARMASERVICE SA	29/03/2023

Αριθμός 4283

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
023025	RISPERIDONE AUROBINDO TABLET, FILM COATED 1MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023026	RISPERIDONE AUROBINDO TABLET, FILM COATED 2MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023027	RISPERIDONE AUROBINDO TABLET, FILM COATED 3MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023028	RISPERIDONE AUROBINDO TABLET, FILM COATED 4MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023795	KABIVIT ORAL DROPS SOLUTION 14.400 IU/ML	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	Επ' αόριστον
022865	NAIREM TABLET, FILM COATED 10MG	DEMO S.A.	Επ' αόριστον
022866	NAIREM TABLET, FILM COATED 20MG	DEMO S.A.	Επ' αόριστον
022864	NAIREM TABLET, FILM COATED 5MG	DEMO S.A.	Επ' αόριστον
022870	RECTOGESIC RECTAL OINTMENT 4MG/G	KYOWA KIRIN HOLDINGS B.V.	Επ' αόριστον
023016	CINACALCET/PHARMAZAC TABLET, FILM COATED 30MG	PHARMAZAC S.A.	Επ' αόριστον
023017	CINACALCET/PHARMAZAC TABLET, FILM COATED 60MG	PHARMAZAC S.A.	Επ' αόριστον
023018	CINACALCET/PHARMAZAC TABLET, FILM COATED 90MG	PHARMAZAC S.A.	Επ' αόριστον
022926	PROPESS VAGINAL DELIVERY SYSTEM 10MG/UNIT	FERRING HELLAS MEPE	Επ' αόριστον
022646	FEBUXOSTAT RONTIS TABLET, FILM COATED 120MG	RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.	Επ' αόριστον
022645	FEBUXOSTAT RONTIS TABLET, FILM COATED 80MG	RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.	Επ' αόριστον
023394	CINACALCET/RAFARM TABLET, FILM COATED 30MG	RAFARM S.A.	Επ' αόριστον
023395	CINACALCET/RAFARM TABLET, FILM COATED 60MG	RAFARM S.A.	Επ' αόριστον
023396	CINACALCET/RAFARM TABLET, FILM COATED 90MG	RAFARM S.A.	Επ' αόριστον

023053	CALRECIA SOLUTION FOR INFUSION 100MMOL/L	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	Επ' αόριστον
022709	BYSIMIN SOLUTION FOR INJECTION 20MG/ML	MEDOCHEMIE LTD	Επ' αόριστον
023359	FIXAPROST EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (50MCG/5MG)/ML	LABORATOIRES THEA	Επ' αόριστον
022712	MICROLAX RECTAL SOLUTION (0.45G/0.0645G/4.465G)/DOSE	JOHNSON & JOHNSON HELLAS CONSUMER AE	Επ' αόριστον
023565	TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023566	TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023563	TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023564	TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022919	APREDONAV TABLET, FILM COATED 5MG	MEDOCHEMIE LTD	Επ' αόριστον
022918	APREDONAV TABLET, FILM COATED 7.5MG	MEDOCHEMIE LTD	Επ' αόριστον
022912	APEL TABLET, FILM COATED 600MG	MEDOCHEMIE LTD	Επ' αόριστον
023512	TEGLUTIK ORAL SUSPENSION 5MG/ML	ITF HELLAS A.E.	Επ' αόριστον
022684	HIREMON EMULSION FOR INFUSION 20MG/ML	DEMO S.A.	Επ' αόριστον
022683	HIREMON EMULSION FOR INJECTION / INFUSION 10MG/ML	DEMO S.A.	Επ' αόριστον
022360	DICLODUO COMBI MODIFIED-RELEASE CAPSULE, HARD	PHARMASWISS CESKA REPUBLIKA SRO	Επ' αόριστον
022778	RAFUSTER CAPSULE, SOFT 0.5MG	RAFARM S.A.	Επ' αόριστον
022565	CLOZAPINE ACCORD TABLET 100MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022564	CLOZAPINE ACCORD TABLET 25MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022642	VIACORAM TABLET 3.5MG/2.5MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022643	VIACORAM TABLET 7MG/5MG	LES LABORATOIRES SERVIER	Επ' αόριστον
023744	VALGANCICLOVIR PHARMATHEN TABLET, FILM COATED 450MG	PHARMATHEN S.A.	Επ' αόριστον
022474	OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 10MG	JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
022475	OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 20MG	JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
022476	OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 40MG	JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
023246	ALENDRONIC ACID AUROBINDO TABLET 70MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον

022533	TOPRISAN TABLET, FILM COATED 50MG	MEDOCHEMIE LTD	Επ' αόριστον
023462	DASATINIB/TEVA TABLET, FILM COATED 100MG	TEVA BV	Επ' αόριστον
023459	DASATINIB/TEVA TABLET, FILM COATED 20MG	TEVA BV	Επ' αόριστον
023460	DASATINIB/TEVA TABLET, FILM COATED 50MG	TEVA BV	Επ' αόριστον
023461	DASATINIB/TEVA TABLET, FILM COATED 70MG	TEVA BV	Επ' αόριστον
023661	LENALIDOMIDE NORAMEDA CAPSULE, HARD 10MG	UAB NORAMEDA	Επ' αόριστον
023662	LENALIDOMIDE NORAMEDA CAPSULE, HARD 15MG	UAB NORAMEDA	Επ' αόριστον
023663	LENALIDOMIDE NORAMEDA CAPSULE, HARD 25MG	UAB NORAMEDA	Επ' αόριστον
023660	LENALIDOMIDE NORAMEDA CAPSULE, HARD 5MG	UAB NORAMEDA	Επ' αόριστον
022847	YASMIN TABLET, FILM COATED 0.03MG/3MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022686	FORVEL SOLUTION FOR INJECTION OR INFUSION 0.4MG/ML	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023000	THYROFIX TABLET 112MCG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023001	THYROFIX TABLET 125MCG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023002	THYROFIX TABLET 137MCG	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	Επ' αόριστον
022997	THYROFIX TABLET 13MCG	DEMO S.A.	Επ' αόριστον
023003	THYROFIX TABLET 150MCG	DEMO S.A.	Επ' αόριστον
023004	THYROFIX TABLET 175MCG	DEMO S.A.	Επ' αόριστον
023005	THYROFIX TABLET 200MCG	KYOWA KIRIN HOLDINGS B.V.	Επ' αόριστον
022998	THYROFIX TABLET 62MCG	PHARMAZAC S.A.	Επ' αόριστον
022999	THYROFIX TABLET 88MCG	PHARMAZAC S.A.	Επ' αόριστον
023025	RISPERIDONE AUROBINDO TABLET, FILM COATED 1MG	PHARMAZAC S.A.	Επ' αόριστον
023026	RISPERIDONE AUROBINDO TABLET, FILM COATED 2MG	FERRING HELLAS MEPE	Επ' αόριστον
023027	RISPERIDONE AUROBINDO TABLET, FILM COATED 3MG	RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.	Επ' αόριστον
023028	RISPERIDONE AUROBINDO TABLET, FILM COATED 4MG	RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.	Επ' αόριστον
023795	KABIVIT ORAL DROPS SOLUTION 14.400 IU/ML	RAFARM S.A.	Επ' αόριστον
022865	NAIREM TABLET, FILM COATED 10MG	RAFARM S.A.	Επ' αόριστον
022866	NAIREM TABLET, FILM COATED 20MG	RAFARM S.A.	Επ' αόριστον

022864	NAIREM TABLET, FILM COATED 5MG	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	Επ' αόριστον
022870	RECTOGESIC RECTAL OINTMENT 4MG/G	MEDOCHEMIE LTD	Επ' αόριστον
023016	CINACALCET/PHARMAZAC TABLET, FILM COATED 30MG	LABORATOIRES THEA	Επ' αόριστον
023017	CINACALCET/PHARMAZAC TABLET, FILM COATED 60MG	JOHNSON & JOHNSON HELLAS CONSUMER AE	Επ' αόριστον
023018	CINACALCET/PHARMAZAC TABLET, FILM COATED 90MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022926	PROPESS VAGINAL DELIVERY SYSTEM 10MG/UNIT	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022646	FEBUXOSTAT RONTIS TABLET, FILM COATED 120MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022645	FEBUXOSTAT RONTIS TABLET, FILM COATED 80MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023394	CINACALCET/RAFARM TABLET, FILM COATED 30MG	MEDOCHEMIE LTD	Επ' αόριστον
023395	CINACALCET/RAFARM TABLET, FILM COATED 60MG	MEDOCHEMIE LTD	Επ' αόριστον
023396	CINACALCET/RAFARM TABLET, FILM COATED 90MG	MEDOCHEMIE LTD	Επ' αόριστον
023053	CALRECIA SOLUTION FOR INFUSION 100MMOL/L	ITF HELLAS A.E.	Επ' αόριστον
022709	BYSIMIN SOLUTION FOR INJECTION 20MG/ML	DEMO S.A.	Επ' αόριστον
023359	FIXAPROST EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (50MCG/5MG)/ML	DEMO S.A.	Επ' αόριστον
022712	MICROLAX RECTAL SOLUTION (0.45G/0.0645G/4.465G)/DOSE	PHARMASWISS CESKA REPUBLIKA SRO	Επ' αόριστον
023565	TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	RAFARM S.A.	Επ' αόριστον
023566	TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023563	TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023564	TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022919	APREDONAV TABLET, FILM COATED 5MG	LES LABORATOIRES SERVIER	Επ' αόριστον
022918	APREDONAV TABLET, FILM COATED 7.5MG	PHARMATHEN S.A.	Επ' αόριστον
022912	APEL TABLET, FILM COATED 600MG	JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
023512	TEGLUTIK ORAL SUSPENSION 5MG/ML	JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
022684	HIREMON EMULSION FOR INFUSION 20MG/ML	JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
022683	HIREMON EMULSION FOR INJECTION / INFUSION 10MG/ML	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον

022360	DICLODUO COMBI MODIFIED-RELEASE CAPSULE, HARD	MEDOCHEMIE LTD	Επ' αόριστον
022778	RAFUSTER CAPSULE, SOFT 0.5MG	TEVA BV	Επ' αόριστον
022565	CLOZAPINE ACCORD TABLET 100MG	TEVA BV	Επ' αόριστον
022564	CLOZAPINE ACCORD TABLET 25MG	TEVA BV	Επ' αόριστον
022642	VIACORAM TABLET 3.5MG/2.5MG	TEVA BV	Επ' αόριστον
022643	VIACORAM TABLET 7MG/5MG	UAB NORAMEDA	Επ' αόριστον
023744	VALGANCICLOVIR PHARMATHEN TABLET, FILM COATED 450MG	UAB NORAMEDA	Επ' αόριστον
022474	OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 10MG	UAB NORAMEDA	Επ' αόριστον
022475	OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 20MG	UAB NORAMEDA	Επ' αόριστον
022476	OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 40MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023246	ALENDRONIC ACID AUROBINDO TABLET 70MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022533	TOPRISAN TABLET, FILM COATED 50MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023462	DASATINIB/TEVA TABLET, FILM COATED 100MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023459	DASATINIB/TEVA TABLET, FILM COATED 20MG	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	Επ' αόριστον
023460	DASATINIB/TEVA TABLET, FILM COATED 50MG	DEMO S.A.	Επ' αόριστον
023461	DASATINIB/TEVA TABLET, FILM COATED 70MG	DEMO S.A.	Επ' αόριστον
023661	LENALIDOMIDE NORAMEDA CAPSULE, HARD 10MG	DEMO S.A.	Επ' αόριστον
023662	LENALIDOMIDE NORAMEDA CAPSULE, HARD 15MG	KYOWA KIRIN HOLDINGS B.V.	Επ' αόριστον
023663	LENALIDOMIDE NORAMEDA CAPSULE, HARD 25MG	PHARMAZAC S.A.	Επ' αόριστον
023660	LENALIDOMIDE NORAMEDA CAPSULE, HARD 5MG	PHARMAZAC S.A.	Επ' αόριστον
022847	YASMIN TABLET, FILM COATED 0.03MG/3MG	PHARMAZAC S.A.	Επ' αόριστον
022686	FORVEL SOLUTION FOR INJECTION OR INFUSION 0.4MG/ML	FERRING HELLAS MEPE	Επ' αόριστον
023000	THYROFIX TABLET 112MCG	RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.	Επ' αόριστον
023001	THYROFIX TABLET 125MCG	RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.	Επ' αόριστον
023002	THYROFIX TABLET 137MCG	RAFARM S.A.	Επ' αόριστον
022997	THYROFIX TABLET 13MCG	RAFARM S.A.	Επ' αόριστον

023003	THYROFIX TABLET 150MCG	RAFARM S.A.	Επ' αόριστον
023004	THYROFIX TABLET 175MCG	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	Επ' αόριστον
023005	THYROFIX TABLET 200MCG	MEDOCHEMIE LTD	Επ' αόριστον
022998	THYROFIX TABLET 62MCG	LABORATOIRES THEA	Επ' αόριστον
022999	THYROFIX TABLET 88MCG	JOHNSON & JOHNSON HELLAS CONSUMER AE	Επ' αόριστον
023025	RISPERIDONE AUROBINDO TABLET, FILM COATED 1MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023026	RISPERIDONE AUROBINDO TABLET, FILM COATED 2MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023027	RISPERIDONE AUROBINDO TABLET, FILM COATED 3MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023028	RISPERIDONE AUROBINDO TABLET, FILM COATED 4MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023795	KABIVIT ORAL DROPS SOLUTION 14.400 IU/ML	MEDOCHEMIE LTD	Επ' αόριστον
022865	NAIREM TABLET, FILM COATED 10MG	MEDOCHEMIE LTD	Επ' αόριστον
022866	NAIREM TABLET, FILM COATED 20MG	MEDOCHEMIE LTD	Επ' αόριστον
022864	NAIREM TABLET, FILM COATED 5MG	ITF HELLAS A.E.	Επ' αόριστον
022870	RECTOGESIC RECTAL OINTMENT 4MG/G	DEMO S.A.	Επ' αόριστον
023016	CINACALCET/PHARMAZAC TABLET, FILM COATED 30MG	DEMO S.A.	Επ' αόριστον
023017	CINACALCET/PHARMAZAC TABLET, FILM COATED 60MG	PHARMASWISS CESKA REPUBLIKA SRO	Επ' αόριστον
023018	CINACALCET/PHARMAZAC TABLET, FILM COATED 90MG	RAFARM S.A.	Επ' αόριστον
022926	PROPESS VAGINAL DELIVERY SYSTEM 10MG/UNIT	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022646	FEBUXOSTAT RONTIS TABLET, FILM COATED 120MG	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022645	FEBUXOSTAT RONTIS TABLET, FILM COATED 80MG	LES LABORATOIRES SERVIER	Επ' αόριστον
023394	CINACALCET/RAFARM TABLET, FILM COATED 30MG	LES LABORATOIRES SERVIER	Επ' αόριστον
023395	CINACALCET/RAFARM TABLET, FILM COATED 60MG	PHARMATHEN S.A.	Επ' αόριστον
023396	CINACALCET/RAFARM TABLET, FILM COATED 90MG	JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
023053	CALRECIA SOLUTION FOR INFUSION 100MMOL/L	JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
022709	BYSIMIN SOLUTION FOR INJECTION 20MG/ML	JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
023359	FIXAPROST EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (50MCG/5MG)/ML	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον

022712	MICROLAX RECTAL SOLUTION (0.45G/0.0645G/4.465G)/DOSE	MEDOCHEMIE LTD	Επ' αόριστον
023565	TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	TEVA BV	Επ' αόριστον
023566	TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	TEVA BV	Επ' αόριστον
023563	TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	TEVA BV	Επ' αόριστον
023564	TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	TEVA BV	Επ' αόριστον
022919	APREDONAV TABLET, FILM COATED 5MG	UAB NORAMEDA	Επ' αόριστον
022918	APREDONAV TABLET, FILM COATED 7.5MG	UAB NORAMEDA	Επ' αόριστον
022912	APEL TABLET, FILM COATED 600MG	UAB NORAMEDA	Επ' αόριστον
023512	TEGLUTIK ORAL SUSPENSION 5MG/ML	UAB NORAMEDA	Επ' αόριστον
022684	HIREMON EMULSION FOR INFUSION 20MG/ML	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022683	HIREMON EMULSION FOR INJECTION / INFUSION 10MG/ML	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022360	DICLODUO COMBI MODIFIED-RELEASE CAPSULE, HARD	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022778	RAFUSTER CAPSULE, SOFT 0.5MG	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
022565	CLOZAPINE ACCORD TABLET 100MG	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	Επ' αόριστον
022564	CLOZAPINE ACCORD TABLET 25MG	DEMO S.A.	Επ' αόριστον
022642	VIACORAM TABLET 3.5MG/2.5MG	DEMO S.A.	Επ' αόριστον
022643	VIACORAM TABLET 7MG/5MG	DEMO S.A.	Επ' αόριστον
023744	VALGANCICLOVIR PHARMATHEN TABLET, FILM COATED 450MG	KYOWA KIRIN HOLDINGS B.V.	Επ' αόριστον
022474	OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 10MG	PHARMAZAC S.A.	Επ' αόριστον
022475	OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 20MG	PHARMAZAC S.A.	Επ' αόριστον
022476	OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 40MG	PHARMAZAC S.A.	Επ' αόριστον
023246	ALENDRONIC ACID AUROBINDO TABLET 70MG	FERRING HELLAS MEPE	Επ' αόριστον
022533	TOPRISAN TABLET, FILM COATED 50MG	RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.	Επ' αόριστον
023462	DASATINIB/TEVA TABLET, FILM COATED 100MG	RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.	Επ' αόριστον
023459	DASATINIB/TEVA TABLET, FILM COATED 20MG	RAFARM S.A.	Επ' αόριστον

023460	DASATINIB/TEVA TABLET, FILM COATED 50MG	RAFARM S.A.	Επ' αόριστον
023461	DASATINIB/TEVA TABLET, FILM COATED 70MG	RAFARM S.A.	Επ' αόριστον
023661	LENALIDOMIDE NORAMEDA CAPSULE, HARD 10MG	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	Επ' αόριστον
023662	LENALIDOMIDE NORAMEDA CAPSULE, HARD 15MG	MEDOCHEMIE LTD	Επ' αόριστον
023663	LENALIDOMIDE NORAMEDA CAPSULE, HARD 25MG	LABORATOIRES THEA	Επ' αόριστον
023660	LENALIDOMIDE NORAMEDA CAPSULE, HARD 5MG	JOHNSON & JOHNSON HELLAS CONSUMER AE	Επ' αόριστον
022847	YASMIN TABLET, FILM COATED 0.03MG/3MG	BAYER HELLAS ABEE	Επ' αόριστον
022686	FORVEL SOLUTION FOR INJECTION OR INFUSION 0.4MG/ML	MEDOCHEMIE LTD	Επ' αόριστον
023000	THYROFIX TABLET 112MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
023001	THYROFIX TABLET 125MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
023002	THYROFIX TABLET 137MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
022997	THYROFIX TABLET 13MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
023003	THYROFIX TABLET 150MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
023004	THYROFIX TABLET 175MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
023005	THYROFIX TABLET 200MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
022998	THYROFIX TABLET 62MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
022999	THYROFIX TABLET 88MCG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
021967	AFLUON EYE DROPS, SOLUTION 0.05%	VIATRIS HEALTHCARE LIMITED.	Επ' αόριστον
021915	DELIPOST TABLET, FILM COATED 10MG	RAFARM S.A.	Επ' αόριστον
021916	DELIPOST TABLET, FILM COATED 20MG	RAFARM S.A.	Επ' αόριστον
021917	DELIPOST TABLET, FILM COATED 40MG	RAFARM S.A.	Επ' αόριστον
021062	MIRATON TABLET 2MG	CODAL-SYNTO LIMITED	Επ' αόριστον
022760	SORIL-MED HONEY & LEMON LOZENGE 0.60MG/1.20MG	SAPIENS PHARMACEUTICALS LTD	Επ' αόριστον
022759	SORIL-MED LEMON LOZENGE 3MG	SAPIENS PHARMACEUTICALS LTD	Επ' αόριστον
022761	SORIL-MED ORANGE LOZENGE 2MG/0.60MG/1.20MG	SAPIENS PHARMACEUTICALS LTD	Επ' αόριστον

Αριθμός 4284

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 (Ν. 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
023822	DEXAMETHASONE MEDOCHEMIE SOLUTION FOR INJECTION OR INFUSION 4MG/ML	DEXAMETHASONE SODIUM PHOSPHATE	MEDOCHEMIE IBERIA S.A.	02/06/2023
023824	PROVIST-OPTO EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 5MG/ML	PREDNISOLONE SODIUM PHOSPHATE	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	02/06/2023
023762	FLUDEOXYGLUCOSE (18F) GE HEALTHCARE SOLUTION FOR INJECTION 250MBQ/ML	FLUDEOXYGLUCOSE	GE HEALTHCARE B.V.	03/01/2023
023792	INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGES 10.000 ANTI-XA IU/0.5ML	TINZAPARIN SODIUM	LEO PHARMA A/S	03/04/2023
023793	INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGES 14.000 ANTI-XA IU/0.7ML	TINZAPARIN SODIUM	LEO PHARMA A/S	03/04/2023
023794	INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGES 18.000 ANTI-XA IU/0.9ML	TINZAPARIN SODIUM	LEO PHARMA A/S	03/04/2023
023791	INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGES 4.500 ANTI-XA IU/0.45ML	TINZAPARIN SODIUM	LEO PHARMA A/S	03/04/2023
023795	KABIVIT ORAL DROPS SOLUTION 14.400 IU/ML	COLECALCIFEROL	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	04/04/2023
023799	TESTOGEL TRANSDERMAL GEL 16.2 MG/G	TESTOSTERONE	LABORATOIRES BESINS INTERNATIONAL	05/04/2023
023800	AROGIO TABLET, FILM COATED 14MG	TERIFLUNOMIDE	ELPEN PHARMACEUTICAL CO INC	06/04/2023
023801	PAGELTRA TABLET, FILM COATED 12.5MG	ELTROMBOPAG OLAMINE	ELPEN PHARMACEUTICAL CO INC	06/04/2023
023802	PAGELTRA TABLET, FILM COATED 25MG	ELTROMBOPAG OLAMINE	ELPEN PHARMACEUTICAL CO INC	06/04/2023
023803	PAGELTRA TABLET, FILM COATED 50MG	ELTROMBOPAG OLAMINE	ELPEN PHARMACEUTICAL CO INC	06/04/2023
023804	PAGELTRA TABLET, FILM COATED 75MG	ELTROMBOPAG OLAMINE	ELPEN PHARMACEUTICAL CO INC	06/04/2023
023770	NEFILIN MODIFIED-RELEASE TABLET 6MG/0.4MG	SOLIFENACIN SUCCINATE	ELPEN PHARMACEUTICAL CO INC	07/02/2023
023770	NEFILIN MODIFIED-RELEASE TABLET 6MG/0.4MG	TAMSULOSIN HYDROCHLORIDE	ELPEN PHARMACEUTICAL CO INC	07/02/2023
023769	TERGIO TABLET, FILM COATED 14MG	TERIFLUNOMIDE	VIATRIS LIMITED	07/02/2023

023772	LACOSAMIDE FRESENIUS KABI SOLUTION FOR INFUSION 10MG/ML	LACOSAMIDE	FRESENIUS KABI HELLAS A.E.	08/02/2023
023771	MERIOFERT PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 900IU/VIAL	MENOTROPHIN	IBSA FARMACEUTICI ITALIA SRL	08/02/2023
023764	TUTECVI COMBI TABLET, FILM COATED 50MG/1000MG	METFORMIN HYDROCHLORIDE	VIATRIS LIMITED	09/01/2023
023764	TUTECVI COMBI TABLET, FILM COATED 50MG/1000MG	VILDAGLIPTIN	VIATRIS LIMITED	09/01/2023
023763	TUTECVI COMBI TABLET, FILM COATED 50MG/850MG	METFORMIN HYDROCHLORIDE	VIATRIS LIMITED	09/01/2023
023763	TUTECVI COMBI TABLET, FILM COATED 50MG/850MG	VILDAGLIPTIN	VIATRIS LIMITED	09/01/2023
023825	TERIFLUNOMIDE MSN TABLET, FILM COATED 14MG	TERIFLUNOMIDE	MSN LABS EUROPE LIMITED	09/06/2023
023807	CARBOPLATIN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	CARBOPLATIN	ACCORD HEALTHCARE S.L.U	11/05/2023
023765	AREGALU TABLET, FILM COATED 14MG	TERIFLUNOMIDE	KRKA D.D. NOVO MESTO	12/01/2023
023805	DINOXIL CUTANEOUS FOAM 50MG/G	MINOXIDIL	IOULIA AND IRENE TSETI PHARMACEUTICAL LABORATORIES S.A.	12/04/2023
023814	HEVASCOL SOLUTION FOR INJECTION 480MG I/ML	ETHYL ESTERS OF IODIZED FATTY ACIDS OF POPPYSEED OIL	GUERBET	12/05/2023
023823	SEHCAT CAPSULE, HARD 370KBQ	TAUROSELCHOLIC ACID	GE HEALTHCARE BUCHLER GMBH & CO KG	13/06/2023
023811	AZITHROMYCIN ALTAN POWDER FOR SOLUTION FOR INFUSION 500MG	AZITHROMYCIN DIHYDRATE	ALTAN PHARMACEUTICALS S.A.	15/05/2023
023820	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	DULOXETINE HYDROCHLORIDE	ACCORD HEALTHCARE S.L.U	15/05/2023
023821	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	DULOXETINE HYDROCHLORIDE	ACCORD HEALTHCARE S.L.U	15/05/2023
023813	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	MACROGOL 4000	CASEN RECORDATI SL	15/05/2023
023812	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 4G	MACROGOL 4000	CASEN RECORDATI SL	15/05/2023
023808	VASPIT TABLET, FILM COATED 1MG	PITAVASTATIN CALCIUM	MEDOCHEMIE LTD	15/05/2023
023809	VASPIT TABLET, FILM COATED 2MG	PITAVASTATIN CALCIUM	MEDOCHEMIE LTD	15/05/2023
023810	VASPIT TABLET, FILM COATED 4MG	PITAVASTATIN CALCIUM	MEDOCHEMIE LTD	15/05/2023
023815	LEFLON TABLET, FILM COATED 15MG	LEFLUNOMIDE	PHARMATHEN S.A.	18/05/2023
023817	PRUCALOPRIDE/WIN MEDICA TABLET, FILM COATED 1MG	PRUCALOPRIDE SUCCINATE	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	18/05/2023

023818	PRUCALOPRIDE/WIN MEDICA TABLET, FILM COATED 2MG	PRUCALOPRIDE SUCCINATE	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	18/05/2023
023816	FINGOLIMOD TECNIGEN CAPSULE, HARD 0.5MG	FINGOLIMOD HYDROCHLORIDE	FARMOZ-SOCIEDADE TECNICO-MEDICINAL,S.A, PORTUGAL	19/05/2023
023827	IBEROGAST N ORAL DROPS LIQUID	CARAWAY	BAYER HELLAS ABEE	19/06/2023
023827	IBEROGAST N ORAL DROPS LIQUID	IBERIS AMARA	BAYER HELLAS ABEE	19/06/2023
023827	IBEROGAST N ORAL DROPS LIQUID	LIQUORICE	BAYER HELLAS ABEE	19/06/2023
023827	IBEROGAST N ORAL DROPS LIQUID	MATRICARIA FLOWER	BAYER HELLAS ABEE	19/06/2023
023827	IBEROGAST N ORAL DROPS LIQUID	MELISSA LEAF	BAYER HELLAS ABEE	19/06/2023
023827	IBEROGAST N ORAL DROPS LIQUID	PEPPERMINT	BAYER HELLAS ABEE	19/06/2023
023767	DABIGATRAN ETEXILATE WIN MEDICA CAPSULE, HARD 110MG	DABIGATRAN ETEXILATE MESILATE	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	20/01/2023
023768	DABIGATRAN ETEXILATE WIN MEDICA CAPSULE, HARD 150MG	DABIGATRAN ETEXILATE MESILATE	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	20/01/2023
023766	DABIGATRAN ETEXILATE WIN MEDICA CAPSULE, HARD 75MG	DABIGATRAN ETEXILATE MESILATE	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	20/01/2023
023828	CEFEPIME APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	CEFEPIME DIHYDROCHLORIDE MONOHYDRATE	APTA MEDICA INTERNACIONAL D.O.O.	20/06/2023
023829	CEFEPIME APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G	CEFEPIME DIHYDROCHLORIDE MONOHYDRATE	APTA MEDICA INTERNACIONAL D.O.O.	20/06/2023
023833	HOPPAS SOLUTION FOR INFUSION 10MG/ML	TREPROSTINIL SODIUM	ELPEN PHARMACEUTICAL CO INC	21/06/2023
023830	HOPPAS SOLUTION FOR INFUSION 1MG/ML	TREPROSTINIL SODIUM	ELPEN PHARMACEUTICAL CO INC	21/06/2023
023831	HOPPAS SOLUTION FOR INFUSION 2.5MG/ML	TREPROSTINIL SODIUM	ELPEN PHARMACEUTICAL CO INC	21/06/2023
023832	HOPPAS SOLUTION FOR INFUSION 5MG/ML	TREPROSTINIL SODIUM	ELPEN PHARMACEUTICAL CO INC	21/06/2023
023826	UTROGESTAN VAGINAL CAPSULE, SOFT 300MG	PROGESTERONE	BESINS HEALTHCARE IRELAND LTD	21/06/2023
023834	PARADIS VAGINAL CAPSULE, HARD	LACTOBACILLUS GASSERI	FREZYDERM S.A.	22/06/2023
023834	PARADIS VAGINAL CAPSULE, HARD	LACTOBACILLUS RHAMNOSUS	FREZYDERM S.A.	22/06/2023
023781	EPIDUO FORTE GEL 0.3%/2.5%	ADAPALENE	GALDERMA INTERNATIONAL,FRANCE	24/03/2023
023781	EPIDUO FORTE GEL 0.3%/2.5%	BENZOYL PEROXIDE	GALDERMA INTERNATIONAL,FRANCE	24/03/2023
023780	VILTIMET TABLET, FILM COATED 50MG/1000MG	METFORMIN HYDROCHLORIDE	ANFARM HELLAS S.A.	28/02/2023
023780	VILTIMET TABLET, FILM COATED 50MG/1000MG	VILDAGLIPTIN	ANFARM HELLAS S.A.	28/02/2023

023779	VILTIMET TABLET, FILM COATED 50MG/850MG	METFORMIN HYDROCHLORIDE	ANFARM HELLAS S.A.	28/02/2023
023779	VILTIMET TABLET, FILM COATED 50MG/850MG	VILDAGLIPTIN	ANFARM HELLAS S.A.	28/02/2023
023798	DIVAMENSTRAL CAPSULE, HARD 226MG	DRYDEX RASBERRY	MEDIS GMBH	29/03/2023
023786	ROSAZIMIB TABLET, FILM COATED 10MG/10MG	EZETIMIBE	KRKA D.D. NOVO MESTO	29/03/2023
023786	ROSAZIMIB TABLET, FILM COATED 10MG/10MG	ROSUVASTATIN CALCIUM	KRKA D.D. NOVO MESTO	29/03/2023
023787	ROSAZIMIB TABLET, FILM COATED 20MG/10MG	EZETIMIBE	KRKA D.D. NOVO MESTO	29/03/2023
023787	ROSAZIMIB TABLET, FILM COATED 20MG/10MG	ROSUVASTATIN CALCIUM	KRKA D.D. NOVO MESTO	29/03/2023
023785	ROSAZIMIB TABLET, FILM COATED 5MG/10MG	EZETIMIBE	KRKA D.D. NOVO MESTO	29/03/2023
023785	ROSAZIMIB TABLET, FILM COATED 5MG/10MG	ROSUVASTATIN CALCIUM	KRKA D.D. NOVO MESTO	29/03/2023
023819	ADDAMEL N NEW CONCENTRATE FOR SOLUTION FOR INFUSION	CHROMIC CHLORIDE HEXAHYDRATE	FRESENIUS KABI HELLAS A.E.	29/05/2023
023819	ADDAMEL N NEW CONCENTRATE FOR SOLUTION FOR INFUSION	COPPER CHLORIDE DIHYDRATE	FRESENIUS KABI HELLAS A.E.	29/05/2023
023819	ADDAMEL N NEW CONCENTRATE FOR SOLUTION FOR INFUSION	FERRIC CHLORIDE HEXAHYDRATE	FRESENIUS KABI HELLAS A.E.	29/05/2023
023819	ADDAMEL N NEW CONCENTRATE FOR SOLUTION FOR INFUSION	MANGANESE CHLORIDE TETRAHYDRATE	FRESENIUS KABI HELLAS A.E.	29/05/2023
023819	ADDAMEL N NEW CONCENTRATE FOR SOLUTION FOR INFUSION	POTASSIUM IODIDE	FRESENIUS KABI HELLAS A.E.	29/05/2023
023819	ADDAMEL N NEW CONCENTRATE FOR SOLUTION FOR INFUSION	SODIUM FLUORIDE	FRESENIUS KABI HELLAS A.E.	29/05/2023
023819	ADDAMEL N NEW CONCENTRATE FOR SOLUTION FOR INFUSION	SODIUM MOLYBDATE DIHYDRATE	FRESENIUS KABI HELLAS A.E.	29/05/2023
023819	ADDAMEL N NEW CONCENTRATE FOR SOLUTION FOR INFUSION	SODIUM SELENITE	FRESENIUS KABI HELLAS A.E.	29/05/2023
023819	ADDAMEL N NEW CONCENTRATE FOR SOLUTION FOR INFUSION	ZINC CHLORIDE	FRESENIUS KABI HELLAS A.E.	29/05/2023
023784	SINVIA TABLET, FILM COATED 100MG	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE	ELPEN PHARMACEUTICAL CO INC	30/03/2023
023782	SINVIA TABLET, FILM COATED 25MG	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE	ELPEN PHARMACEUTICAL CO INC	30/03/2023
023783	SINVIA TABLET, FILM COATED 50MG	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE	ELPEN PHARMACEUTICAL CO INC	30/03/2023
023775	BISOLOC TABLET, FILM COATED 10MG	BISOPROLOL FUMARATE 10. mg	SAPIENS PHARMACEUTICALS LTD	13/02/2023

023773	BISOLOC TABLET, FILM COATED 2.5MG	BISOPROLOL FUMARATE 2.5 mg	SAPIENS PHARMACEUTICALS LTD	13/02/2023
023774	BISOLOC TABLET, FILM COATED 5MG	BISOPROLOL FUMARATE 5. mg	SAPIENS PHARMACEUTICALS LTD	13/02/2023
023835	SUNITINIB SAPIENS CAPSULE, HARD 12.5MG	SUNITINIB 12.5 mg	SAPIENS PHARMACEUTICALS LTD	19/06/2023
023836	SUNITINIB SAPIENS CAPSULE, HARD 25MG	SUNITINIB 25. mg	SAPIENS PHARMACEUTICALS LTD	19/06/2023
023837	SUNITINIB SAPIENS CAPSULE, HARD 37.5MG	SUNITINIB 37.5 mg	SAPIENS PHARMACEUTICALS LTD	19/06/2023
023838	SUNITINIB SAPIENS CAPSULE, HARD 50MG	SUNITINIB 50. mg	SAPIENS PHARMACEUTICALS LTD	19/06/2023
023797	DEFERIPRONE SAPIENS TABLET, FILM COATED 1000MG	DEFERIPRONE 1000. mg	SAPIENS PHARMACEUTICALS LTD	22/03/2023
023796	DEFERIPRONE SAPIENS TABLET, FILM COATED 500MG	DEFERIPRONE 500. mg	SAPIENS PHARMACEUTICALS LTD	22/03/2023
023789	EDOLFEN DUAL ACTION TABLET, FILM COATED 200MG/500MG	IBUPROFEN 200. mg | PARACETAMOL 500. mg	REMEDICA LTD	27/03/2023
023790	LAPREM TABLET, FILM COATED 250MG	LAPATINIB DITOSYLATE MONOHYDRATE 405. mg	REMEDICA LTD	27/03/2023
023788	SUGAMMADEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	SUGAMMADEX SODIUM 108.8 mg	SAPIENS PHARMACEUTICALS LTD	27/03/2023

Αριθμός 4285

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
S01296	DORMIPNOL SOLUTION FOR INJECTION 5MG/ML	MIDAZOLAM	VIOFAR LTD	18/01/2023
S01295	ERYTHROMYCIN INRESA POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	ERYTHROMYCIN LACTOBIONATE	INRESA ARZNEIMITTEL GMBH	18/01/2023
S01301	BUPIVACAINE AGUETTANT SOLUTION FOR INJECTION 5MG/ML	BUPIVACAINE HYDROCHLORIDE, MONOHYDRATE	SAPIENS PHARMACEUTICALS LTD	21/06/2023
S01300	EPHEDRINE AGUETTANT SOLUTION FOR INJECTION 30MG/ML	EPHEDRINE HYDROCHLORIDE	SAPIENS PHARMACEUTICALS LTD	21/06/2023
S01303	EPIXIVAL SOLUTION FOR INJECTION 100MG/ML	VALPROATE SODIUM	PHARMA BAVARIA INTERNACIONAL (PBI) PORTUGAL UNIPESSOAL LDA.	21/06/2023
S01302	MIOCHOL-E POWDER AND SOLVENT FOR INTRAOCULAR INSTILLATION SOLUTION 1% W/V	ACETYLCHOLINE CHLORIDE	DR.GERHARD MANN CHEM.-PHARM. FABRIK GMBH	21/06/2023
S01299	HEPARIN SODIUM 10 I.U./ML FLUSHING SOLUTION FOR MAINTENANCE OF PATENCY OF INTRAVENOUS DEVICES FLUSHING SOLUTION 10IU/ML	HEPARIN SODIUM	WOCKHARDT UK LTD	22/03/2023
S01297	FENTANYL RENAUDIN SOLUTION FOR INJECTION 50MCG/ML			
S01298	PARVOLEX CONCENTRATE FOR SOLUTION FOR INFUSION 200MG/ML			

Αριθμός 4286

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 (Ν. 70(Ι)/2001) όπως εκάστοτε τροποποιείται, ενέκρινε τις πιο κάτω τροποποιήσεις:

Όνομα ΦΠ	Αρ. Πρωτοκ.	Αρ. ΑΚ	ΚΑΚ	Περιγρ. Τροπ.
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 25MG	1860/23Τ	1860/23Τ	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
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 50MG	1863/23Τ	1863/23Τ	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
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 100MG	1858/23Τ	1858/23Τ	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
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 150MG	1862/23Τ	1862/23Τ	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

PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 75MG	1859/23T	1859/23T	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
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 100MG AND 150MG	1861/23T	1861/23T	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
BETAHISTINE AUROBINDO TABLET 8MG	3171/23T, 3172/23T	3171/23T, 3172/23T	AUROBINDO PHARMA (MALTA) 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

IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	3028/23T	3028/23T	ACCORD HEALTHCARE S.L.U	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
IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	3026/23T	3026/23T	ACCORD HEALTHCARE S.L.U	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
IDARUBICIN ACCORD SOLUTION FOR INJECTION 10MG/10ML	3027/23T	3027/23T	ACCORD HEALTHCARE S.L.U	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
PRODUODOPA SOLUTION FOR INFUSION (240MG+12MG)/ML	1927/23T	1927/23T	ABBVIE PHARMACEUTICALS S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	964/23T, 965/23T	964/23T, 965/23T	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
SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	962/23T, 963/23T	962/23T, 963/23T	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
OCTAGAM SOLUTION FOR INFUSION 10%	3072/23T, 3073/23T, 3074/23T	3072/23T, 3073/23T, 3074/23T	OCTAPHARMA (IP) SPRL	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 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 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
NICORETTE QUICKSPRAY OROMUCOSAL SPRAY, SOLUTION 1MG/DOSE	4514/23T	4514/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
IMODIUM PLUS TABLET 2MG/125MG	4513/23T	4513/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	4512/23T	4512/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01MG/ML	2779/23T	2779/23T	INIBSA DENTAL 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
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01MG/ML	2779/23T	2779/23T	INIBSA DENTAL 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
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005MG/ML	2778/23T	2778/23T	INIBSA DENTAL 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
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005MG/ML	2778/23T	2778/23T	INIBSA DENTAL 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
NOVANTRONE CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/ML	6938/22T	6938/22T	VIATRIS 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
OLIMEL PERI N4E EMULSION FOR INFUSION	2890/23T	2890/23T	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	2888/23T	2888/23T	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	2887/23T	2887/23T	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	2889/23T	2889/23T	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
MECOLZINE TABLET, GASTRO-RESISTANT 500MG	8169/22T	8169/22T	FAES FARMA SA	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
TYBETA TABLET, FILM COATED 50MG	4756/23T	4756/23T	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)*
TYBETA TABLET, FILM COATED 25MG	4757/23T	4757/23T	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)*
TYBETA TABLET, FILM COATED 100MG	4755/23T	4755/23T	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)*
AMIKACIN/KABI SOLUTION FOR INFUSION 5MG/ML	3991/23T, 3992/23T	3991/23T, 3992/23T	FRESENIUS KABI HELLAS SINGLE MEMBER 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 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
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 50U	5410/23T	5410/23T	MERZ PHARMACEUTICALS 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
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 100U	5409/23T	5409/23T	MERZ PHARMACEUTICALS 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

SMOFKABIVEN EMULSION FOR INFUSION	4222/23T, 4223/23T, 4224/23T, 4225/23T, 4226/23T, 4227/23T	4222/23T, 4223/23T, 4224/23T, 4225/23T, 4226/23T, 4227/23T	FRESENIUS KABI HELLAS 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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 LOW OSMO PERIPHERAL EMULSION FOR INFUSION	4210/23T, 4211/23T, 4212/23T, 4213/23T, 4214/23T, 4215/23T	4210/23T, 4211/23T, 4212/23T, 4213/23T, 4214/23T, 4215/23T	FRESENIUS KABI HELLAS 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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 PERIPHERAL EMULSION FOR INFUSION	4216/23T, 4217/23T, 4218/23T, 4219/23T, 4220/23T, 4221/23T	4216/23T, 4217/23T, 4218/23T, 4219/23T, 4220/23T, 4221/23T	FRESENIUS KABI HELLAS 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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an

				active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 EMULSION FOR INFUSION	4204/23T, 4205/23T, 4206/23T, 4207/23T, 4208/23T, 4209/23T	4204/23T, 4205/23T, 4206/23T, 4207/23T, 4208/23T, 4209/23T	FRESENIUS KABI HELLAS 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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already

				approved manufacturer
GEODON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 20MG/ML	4281/23T, 4282/23T	4281/23T, 4282/23T	UPJOHN HELLAS LTD	B.I.c.1.z B.I.c.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Container closure system - Change in immediate packaging of the active substance - Other changes 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
PARIET TABLET, GASTRO-RESISTANT 10MG	4111/23T	4111/23T	JANSSEN-CILAG INTERNATIONAL NV	C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in the legal status of a medicinal product for centrally authorised products - Other variation
PARIET TABLET, GASTRO-RESISTANT 20MG	4112/23T	4112/23T	JANSSEN-CILAG INTERNATIONAL NV	C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in the legal status of a medicinal product for centrally authorised products - Other variation
SANDIMMUN NEORAL CAPSULE, SOFT 100MG	4643/23T	4643/23T	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)*
SANDIMMUN NEORAL CAPSULE, SOFT 25MG	4645/23T	4645/23T	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)*
SANDIMMUN NEORAL CAPSULE, SOFT 50MG	4644/23T	4644/23T	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)*
ENCAPIA TABLET, FILM COATED 200MG	4251/23T	4251/23T	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
REMEDOL TABLET 500MG	4800/23T	4800/23T	REMEDICA LTD	C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in the legal status of a medicinal product for centrally authorised products - Other variation
PARACETAMOL-REMEDICA TABLET 500MG	4802/23T	4802/23T	REMEDICA LTD	C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in the legal status of a medicinal product for centrally authorised products - Other variation
REMEDOL FC TABLET, FILM COATED 500MG	4801/23T	4801/23T	REMEDICA LTD	C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in the legal status of a medicinal product for centrally authorised products - Other variation

OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	1767/23T	1767/23T	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
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 1000IU	1766/23T	1766/23T	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
ATORVASTATIN ACCORD TABLET, FILM COATED 10MG	3170/23T	3170/23T	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
ATORVASTATIN ACCORD TABLET, FILM COATED 20MG	3169/23T	3169/23T	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
ATORVASTATIN ACCORD TABLET, FILM COATED 40MG	3168/23T	3168/23T	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
OLANZAPINE AUROBINDO TABLET 5MG	4088/23T, 4089/23T	4088/23T, 4089/23T	AUROBINDO PHARMA (MALTA) 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.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
OLANZAPINE AUROBINDO TABLET 10MG	4086/23T, 4087/23T	4086/23T, 4087/23T	AUROBINDO PHARMA (MALTA) 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.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
DENAZOX TABLET 60MG	3955/23T	3955/23T	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
SMOFKABIVEN EMULSION FOR INFUSION	8879/22T, 8880/22T, 8881/22T, 8882/22T, 8883/22T, 8884/22T, 8885/22T, 8886/22T, 8887/22T, 8888/22T, 8889/22T, 8890/22T, 8891/22T	8879/22T, 8880/22T, 8881/22T, 8882/22T, 8883/22T, 8884/22T, 8885/22T, 8886/22T, 8887/22T, 8888/22T, 8889/22T, 8890/22T, 8891/22T	FRESENIUS KABI HELLAS SINGLE MEMBER 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.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
SMOFKABIVEN LOW OSMO PERIPHERAL EMULSION FOR INFUSION	8840/22T, 8841/22T, 8842/22T, 8843/22T, 8844/22T, 8845/22T, 8846/22T, 8847/22T, 8848/22T,	8840/22T, 8841/22T, 8842/22T, 8843/22T, 8844/22T, 8845/22T, 8846/22T, 8847/22T, 8848/22T,	FRESENIUS KABI HELLAS SINGLE MEMBER 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

	8849/22T, 8850/22T, 8851/22T, 8852/22T	8849/22T, 8850/22T, 8851/22T, 8852/22T		of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.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
SMOFKABIVEN EXTRA NITROGEN EMULSION FOR INFUSION	8866/22T, 8867/22T, 8868/22T, 8869/22T, 8870/22T, 8871/22T, 8872/22T, 8873/22T, 8874/22T, 8875/22T, 8876/22T, 8877/22T, 8878/22T	8866/22T, 8867/22T, 8868/22T, 8869/22T, 8870/22T, 8871/22T, 8872/22T, 8873/22T, 8874/22T, 8875/22T, 8876/22T, 8877/22T, 8878/22T	FRESENIUS KABI HELLAS SINGLE MEMBER 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.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
SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION	8853/22T, 8854/22T, 8855/22T, 8856/22T, 8857/22T, 8858/22T, 8859/22T, 8860/22T, 8861/22T, 8862/22T, 8863/22T, 8864/22T, 8865/22T	8853/22T, 8854/22T, 8855/22T, 8856/22T, 8857/22T, 8858/22T, 8859/22T, 8860/22T, 8861/22T, 8862/22T, 8863/22T, 8864/22T, 8865/22T	FRESENIUS KABI HELLAS SINGLE MEMBER 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.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
SMOFKABIVEN EMULSION FOR INFUSION	826/23T, 827/23T, 828/23T	826/23T, 827/23T, 828/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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 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
SMOFKABIVEN ELECTROLYTE FREE EMULSION FOR INFUSION	823/23T, 824/23T, 825/23T	823/23T, 824/23T, 825/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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 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
SMOFKABIVEN LOW OSMO PERIPHERAL EMULSION FOR INFUSION	817/23T, 818/23T, 819/23T	817/23T, 818/23T, 819/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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 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
SMOFKABIVEN EXTRA NITROGEN EMULSION FOR INFUSION	814/23T, 815/23T, 816/23T	814/23T, 815/23T, 816/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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 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
SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION	820/23T, 821/23T, 822/23T	820/23T, 821/23T, 822/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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 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
SMOFKABIVEN EXTRA NITROGEN ELECTROLYTE FREE EMULSION FOR INFUSION	811/23T, 812/23T, 813/23T	811/23T, 812/23T, 813/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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 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
ROSU-ASA CAPSULE, HARD 5MG/100MG	3122/23T	3122/23T	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
ROSU-ASA CAPSULE, HARD 10MG/100MG	3121/23T	3121/23T	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
ROSU-ASA CAPSULE, HARD 20MG/100MG	3120/23T	3120/23T	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
NICORETTE QUICKSPRAY OROMUCOSAL SPRAY, SOLUTION 1MG/DOSE	3569/23T	3569/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
REGAINE WOMEN'S FOAM CUTANEOUS FOAM 5% W/W	3570/23T	3570/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	3568/23T	3568/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
STATEZOL TABLET, FILM COATED 10MG/10MG	3777/23T, 3778/23T, 3779/23T, 3780/23T, 3781/23T	3777/23T, 3778/23T, 3779/23T, 3780/23T, 3781/23T	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 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
STATEZOL TABLET, FILM COATED 20MG/10MG	3772/23T, 3773/23T, 3774/23T, 3775/23T, 3776/23T	3772/23T, 3773/23T, 3774/23T, 3775/23T, 3776/23T	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 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
STATEZOL TABLET, FILM COATED 5MG/10MG	3782/23T, 3783/23T, 3784/23T, 3785/23T, 3786/23T	3782/23T, 3783/23T, 3784/23T, 3785/23T, 3786/23T	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 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
STATEZOL TABLET, FILM COATED 40MG/10MG	3767/23T, 3768/23T, 3769/23T, 3770/23T, 3771/23T	3767/23T, 3768/23T, 3769/23T, 3770/23T, 3771/23T	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 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
DELSIMET TABLET, FILM COATED 50MG/1000MG	3412/23T	3412/23T	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
DELSIMET TABLET, FILM COATED 50MG/850MG	3413/23T	3413/23T	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
ATORVASTATIN KRKA TABLET, FILM COATED 60MG	2651/23T, 2652/23T	2651/23T, 2652/23T	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 C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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	2659/23T, 2660/23T	2659/23T, 2660/23T	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 C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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	2653/23T, 2654/23T	2653/23T, 2654/23T	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 C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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	2649/23T, 2650/23T	2649/23T, 2650/23T	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 C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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	2657/23T, 2658/23T	2657/23T, 2658/23T	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 C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal

				products following assessment of the 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 30MG	2655/23T, 2656/23T	2655/23T, 2656/23T	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 C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be

				submitted by the MAH
AVAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 160 ANTIGEN UNITS/0.5ML	3016/23T	3016/23T	SANOFI PASTEUR.	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
AXETINE TABLET, FILM COATED 250MG	4093/23T, 4094/23T	4093/23T, 4094/23T	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
AXETINE TABLET, FILM COATED 500MG	4091/23T, 4092/23T	4091/23T, 4092/23T	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
BILAZ TABLET 20MG	4728/23T	4728/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG 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
PHYSIONEAL 35 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	2099/23T	2099/23T	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
PHYSIONEAL 40 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86%	2095/23T	2095/23T	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
PHYSIONEAL 40 GLUCOSE 2.27% W/V/22.7MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 2.27% W/V	2096/23T	2096/23T	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
PHYSIONEAL 35 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	2100/23T	2100/23T	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
PHYSIONEAL 40 GLUCOSE 1.36% W/V/13.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 1.36% W/V	2097/23T	2097/23T	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
PHYSIONEAL 35 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86% W/V	2098/23T	2098/23T	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
FLUNOL CAPSULE, HARD 100MG	3973/23T	3973/23T	PHARMA Q 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 - Change in the holding time of an intermediate
TESTOGEL GEL 50MG	8746/22T	8746/22T	LABORATOIRES BESINS INTERNATIONAL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TESTOGEL GEL 25MG	8747/22T	8747/22T	LABORATOIRES BESINS INTERNATIONAL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing

				authorisation holder
ZITHROMAX POWDER FOR ORAL SUSPENSION 200MG/5ML	3331/23T, 3332/23T, 3333/23T	3331/23T, 3332/23T, 3333/23T	PFIZER HELLAS 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 - Eur 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.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

BUDENOFALK UNO GASTRO-RESISTANT GRANULES 9MG	4532/23T, 4533/23T, 4534/23T, 4535/23T, 4536/23T, 4537/23T, 4538/23T	4532/23T, 4533/23T, 4534/23T, 4535/23T, 4536/23T, 4537/23T, 4538/23T	DR. FALK PHARMA GMBH	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.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
OCTISET CUTANEOUS SOLUTION	9069/22T	9069/22T	T.C.CHRISTOFOROU 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
OCTISET VAGINAL SOLUTION	9070/22T	9070/22T	T.C.CHRISTOFOROU 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
DELSITA TABLET, FILM COATED 100MG	3456/23T	3456/23T	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
DELSITA TABLET, FILM COATED 25MG	3458/23T	3458/23T	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
DELSITA TABLET, FILM COATED 50MG	3457/23T	3457/23T	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
FLUDEX FILM COATED, PROLONGED RELEASE TABLETS 1.5MG	2852/23T	2852/23T	LES LABORATOIRES SERVIER	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
COVERSYL TABLET, FILM COATED 10MG	2854/23T	2854/23T	LES LABORATOIRES SERVIER	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
COVERSYL TABLET, FILM COATED 5MG	2853/23T	2853/23T	LES LABORATOIRES SERVIER	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

SALOFALK SUPPOSITORY 1G	3683/23T, 3684/23T, 3685/23T, 3686/23T, 3687/23T	3683/23T, 3684/23T, 3685/23T, 3686/23T, 3687/23T	DR. FALK 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.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.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).
MEDOPRAZOLE GASTRO-RESISTANT CAPSULE, HARD 20MG	2795/23T	2795/23T	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
CONTROLOC TABLET, GASTRO-RESISTANT 20MG	4294/23T	4294/23T	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)*
CONTROLOC TABLET, GASTRO-RESISTANT 40MG	4295/23T	4295/23T	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)*
AZOLAM TABLET 0.5MG	2542/23T	2542/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products

AZOLAM TABLET 1MG	2541/23T	2541/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
AZOLAM TABLET 0.25MG	2543/23T	2543/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/500MCG	3956/23T	3956/23T	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/250MCG	3957/23T	3957/23T	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/100MCG	3958/23T	3958/23T	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
FERINJECT DISPERSION FOR INJECTION/INFUSION 50MG IRON/ML	4539/23T, 4540/23T, 4541/23T	4539/23T, 4540/23T, 4541/23T	VIFOR FRANCE	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
GABENIL CAPSULE, HARD 100MG	3799/23T	3799/23T	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)*
GABENIL CAPSULE, HARD 300MG	3798/23T	3798/23T	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)*
GABENIL CAPSULE, HARD 400MG	3797/23T	3797/23T	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)*
COLCHICINE RENATA TABLET 500MCG	2733/23T	2733/23T	RENATA PHARMACEUTICALS (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
VITAROS CREAM 3MG/G	7322/22T	7322/22T	RECORDATI IRELAND LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
VITAROS CREAM 2MG/G	7323/22T	7323/22T	RECORDATI IRELAND LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
METFORMIN ACCORD TABLET, FILM COATED 500MG	4660/23T	4660/23T	ACCORD HEALTHCARE S.L.U	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
METFORMIN ACCORD TABLET, FILM COATED 850MG	4659/23T	4659/23T	ACCORD HEALTHCARE S.L.U	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

PRIMPERAN TABLET 10MG	3173/23T, 3174/23T	3173/23T, 3174/23T	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)* A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PRIMPERAN SOLUTION FOR INJECTION 10MG/2ML	3175/23T, 3176/23T	3175/23T, 3176/23T	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)* A.z A.z - ADMINISTRATIVE CHANGES - Other variation
GABAPENTIN ACCORD CAPSULE, HARD 300MG	4642/23T	4642/23T	ACCORD HEALTHCARE S.L.U	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

GABAPENTIN ACCORD CAPSULE, HARD 400MG	4641/23T	4641/23T	ACCORD HEALTHCARE S.L.U	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
ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	3246/23T	3246/23T	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
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	3247/23T	3247/23T	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
ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	3248/23T	3248/23T	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
ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	3245/23T	3245/23T	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
PROPESS VAGINAL DELIVERY SYSTEM 10MG/UNIT	3397/23T	3397/23T	FERRING HELLAS MEPE	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)
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	2582/23T	2582/23T	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
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	2582/23T	2582/23T	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
ANASTROZOLE ACCORD TABLET, FILM COATED 1MG	3921/23T	3921/23T	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
LOBIVON PLUS TABLET, FILM COATED 5MG/25MG	4132/23T	4132/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG 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
LOBIVON TABLET 5MG	4133/23T	4133/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG 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
LOBIVON PLUS TABLET, FILM COATED 5MG/12.5MG	4131/23T	4131/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG 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/VALSARTAN/HYDROCHLOROTHIAZIDE ELPEN TABLET, FILM COATED 10MG/320MG/25MG	2689/22T	2689/22T	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 5MG/160MG/12.5MG	2687/22T	2687/22T	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/160MG/25MG	2688/22T	2688/22T	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/160MG/25MG	2598/22T	2598/22T	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	2599/22T	2599/22T	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 5MG/160MG/12.5MG	2597/22T	2597/22T	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
REGAINE WOMEN'S FOAM CUTANEOUS FOAM 5% W/W	4712/23T	4712/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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
CLARITHROMYCIN AUROBINDO TABLET, FILM COATED 500MG	3083/23T, 3084/23T	3083/23T, 3084/23T	AUROBINDO PHARMA (MALTA) 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
HYDROCORTISONE RENATA TABLET 20MG	4137/23T	4137/23T	RENATA PHARMACEUTICALS (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)
HYDROCORTISONE RENATA TABLET 10MG	4138/23T	4138/23T	RENATA PHARMACEUTICALS (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)
FERROUS FUMARATE TABLET, FILM COATED 200MG	391/23T, 392/23T, 393/23T	391/23T, 392/23T, 393/23T	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
VISIPAQUE INJECTION 270MGI/ML	9788/22T	9788/22T	GE HEALTHCARE AS (NYDALEN)	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
VISIPAQUE INJECTION 320MGI/ML	9787/22T	9787/22T	GE HEALTHCARE AS (NYDALEN)	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
MEDICORT TABLET 20MG	3801/23T	3801/23T	MEDICAIR BIOSCIENCE LABORATORIES CY 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
MEDICORT TABLET 4MG	3803/23T	3803/23T	MEDICAIR BIOSCIENCE LABORATORIES CY 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
MEDICORT TABLET 8MG	3802/23T	3802/23T	MEDICAIR BIOSCIENCE LABORATORIES CY 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
FLUVASTATIN ACCORD TABLET, PROLONGED-RELEASE 80MG	3269/23T	3269/23T	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
MITOMYCIN ACCORD POWDER FOR SOLUTION FOR INJECTION/INFUSION 20MG/VIAL	3884/23T	3884/23T	ACCORD HEALTHCARE S.L.U	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	3881/23T	3881/23T	ACCORD HEALTHCARE S.L.U	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
PANTOFLUX TABLET, GASTRO-RESISTANT 40MG	118/23T	118/23T	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)*
PANTOFLUX TABLET, GASTRO-RESISTANT 20MG	119/23T	119/23T	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)*
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	1529/23T, 1530/23T	1529/23T, 1530/23T	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 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.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 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
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	1535/23T, 1536/23T	1535/23T, 1536/23T	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 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.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 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
BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	1531/23T, 1532/23T	1531/23T, 1532/23T	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 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.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 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
BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	1533/23T, 1534/23T	1533/23T, 1534/23T	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 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.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 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
APO-GO PFS SOLUTION FOR INFUSION 5MG/ML IN PREFILLED SYRINGE	3871/23T	3871/23T	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
ADAGREL TABLET, FILM COATED 75MG	2714/23T	2714/23T	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
ULTRAVIST 370 SOLUTION FOR INJECTION 76.9%	1967/23T	1967/23T	BAYER HELLAS ABEE	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)
ULTRAVIST 300 SOLUTION FOR INJECTION 62.34%	1968/23T	1968/23T	BAYER HELLAS ABEE	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)
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 100MG/1000MG	1069/23T, 1070/23T	1069/23T, 1070/23T	APC INSTYTUT SP. Z.O.O.	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
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/1000MG	1071/23T, 1072/23T	1071/23T, 1072/23T	APC INSTYTUT SP. Z.O.O.	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
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/500MG	1073/23T, 1074/23T	1073/23T, 1074/23T	APC INSTYTUT SP. Z.O.O.	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
FOLIRON TABLET, FILM COATED 100MG/0.35MG	4274/23T	4274/23T	REMEDICA LTD	C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in the legal status of a medicinal product for centrally authorised products - Other variation
FERROUS FUMARATE TABLET, FILM COATED 200MG	4272/23T	4272/23T	REMEDICA LTD	C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in the legal status of a medicinal product for centrally authorised products - Other variation
PARACETAMOL SAPIENS SOLUTION FOR INFUSION 10MG/ML	1579/23T	1579/23T	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
FERROUS GLUCONATE TABLET, FILM COATED 300MG	4273/23T	4273/23T	REMEDICA LTD	C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in the legal status of a medicinal product for centrally authorised products - Other variation
BILAZ ORAL SOLUTION 2.5MG/ML	7833/22T	7833/22T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
REGAINE WOMEN'S FOAM CUTANEOUS FOAM 5% W/W	9260/22T	9260/22T	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NETENAX EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 3MG/ML	3037/23T	3037/23T	NEWLINE PHARMA, S.L.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
NETENAX EYE DROPS, SOLUTION 3MG/ML	3038/23T	3038/23T	NEWLINE PHARMA, S.L.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BILAZ TABLET, ORODISPERSIBLE 10MG	7832/22T	7832/22T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

CAPOLEV PLUS TABLET 16/12.5MG	3696/23T	3696/23T	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	3697/23T	3697/23T	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 32/12.5MG	3695/23T	3695/23T	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	3694/23T	3694/23T	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)*
SYNTOCLAV TABLET, FILM COATED 875/125MG	3693/23T	3693/23T	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
BETAISODONA ANTISEPTIC PAINT SOLUTION 10% W/V	3978/23T	3978/23T	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
BETAISODONA SKIN CLEANSER CUTANEOUS SOLUTION 4% W/V	3984/23T	3984/23T	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
BETAISODONA ALCOHOLIC CUTANEOUS SOLUTION 10% W/V	3983/23T	3983/23T	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
REMABIRAT TABLET, FILM COATED 250MG	1416/23T	1416/23T	REMEDICA 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
REMABIRAT TABLET, FILM COATED 500MG	1415/23T	1415/23T	REMEDICA 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
MOVATEC TABLET 15MG	9869/22T	9869/22T	BOEHRINGER INGELHEIM INTERNATIONAL 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
MOVATEC TABLET 7.5MG	9868/22T	9868/22T	BOEHRINGER INGELHEIM INTERNATIONAL 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
CLOVELEN TABLET, FILM COATED 75MG	1417/23T, 1418/23T, 1419/23T, 1420/23T	1417/23T, 1418/23T, 1419/23T, 1420/23T	ELPEN PHARMACEUTICAL CO INC	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.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.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
LEVOFLOXACIN NORIDEM SOLUTION FOR INFUSION 5MG/ML	4244/23T, 4245/23T, 4246/23T	4244/23T, 4245/23T, 4246/23T	NORIDEM ENTERPRISES 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
ENGERIX-B PEDIATRIC SUSPENSION FOR INJECTION 10MCG/0.5ML	6529/21T	6529/21T	GLAXOSMITHKLINE BIOLOGICALS SA	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
SPIROLON TABLET, FILM COATED 100MG	4653/23T, 4654/23T, 4655/23T, 4656/23T, 4657/23T, 4658/23T	4653/23T, 4654/23T, 4655/23T, 4656/23T, 4657/23T, 4658/23T	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 bat 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/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.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.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
SPIROLON TABLET, FILM COATED 25MG	4647/23T, 4648/23T, 4649/23T, 4650/23T, 4651/23T, 4652/23T	4647/23T, 4648/23T, 4649/23T, 4650/23T, 4651/23T, 4652/23T	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 bat 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/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.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.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
ROSUVASTATIN ACINO TABLET, FILM COATED 40MG	1792/23T, 1793/23T, 1794/23T, 1795/23T	1792/23T, 1793/23T, 1794/23T, 1795/23T	ACINO 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 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 -
ROSUVASTATIN ACINO TABLET, FILM COATED 20MG	1796/23T, 1797/23T, 1798/23T, 1799/23T	1796/23T, 1797/23T, 1798/23T, 1799/23T	ACINO 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 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 -
ROSUVASTATIN ACINO TABLET, FILM COATED 5MG	1804/23T, 1805/23T, 1806/23T, 1807/23T	1804/23T, 1805/23T, 1806/23T, 1807/23T	ACINO 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 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 -
ROSUVASTATIN ACINO TABLET, FILM COATED 10MG	1800/23T, 1801/23T, 1802/23T, 1803/23T	1800/23T, 1801/23T, 1802/23T, 1803/23T	ACINO 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

				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 -
OLOXICAM SOLUTION FOR INJECTION 10MG/ML	2798/23T, 2799/23T	2798/23T, 2799/23T	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 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 SOLUTION FOR INJECTION 10MG/ML	8614/22T	8614/22T	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
CLAREM TABLET, FILM COATED 500MG	3681/23T	3681/23T	REMEDICA 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
CLAREM TABLET, FILM COATED 250MG	3682/23T	3682/23T	REMEDICA 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

REXANIB TABLET, FILM COATED 200MG	1392/23T	1392/23T	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)
REXANIB TABLET, FILM COATED 400MG	1391/23T	1391/23T	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)
MIRATON TABLET 2MG	3915/22T	3915/22T	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
STRIVERDI RESPIMAT SOLUTION FOR INHALATION	9033/22T	9033/22T	BOEHRINGER INGELHEIM	C.I.11.b C.I.11.b - SAFETY,

			INTERNATIONAL GMBH	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*
NETAXAN EYE GEL (3MG/1MG)/ML	2923/22T	2923/22T	NEWLINE PHARMA, S.L.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
NETAXAN EYE DROPS, SOLUTION (3MG/1MG)/ML	3039/23T	3039/23T	NEWLINE PHARMA, S.L.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
NETAXAN EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (3MG/1MG)/ML	3040/23T	3040/23T	NEWLINE PHARMA, S.L.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
STRIVERDI RESPIMAT SOLUTION FOR INHALATION	1883/23T	1883/23T	BOEHRINGER INGELHEIM	C.I.12 C.I.12 - SAFETY, EFFICACY,

			INTERNATIONAL GMBH	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
YANIMO RESPIMAT SOLUTION FOR INHALATION	9803/21T	9803/21T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SPIRIVA RESPIMAT SOLUTION FOR INHALATION 2.5MCG/PUFF	9801/21T	9801/21T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
STRIVERDI RESPIMAT SOLUTION FOR INHALATION	9804/21T	9804/21T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	9802/21T	9802/21T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NETAXAN EYE GEL (3MG/1MG)/ML	3041/23T	3041/23T	NEWLINE PHARMA, S.L.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LOSARTAN POTASSIUM JUBILANT TABLET, FILM COATED 50MG	3462/23T, 3463/23T	3462/23T, 3463/23T	JUBILANT PHARMACEUTICALS 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
LOSARTAN POTASSIUM JUBILANT TABLET, FILM COATED 50MG	3440/23T, 3441/23T	3440/23T, 3441/23T	JUBILANT PHARMACEUTICALS NV	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.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
GEODON CAPSULE, HARD 20MG	3602/23T	3602/23T	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)*
GEODON CAPSULE, HARD 40MG	3601/23T	3601/23T	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)*
GEODON CAPSULE, HARD 60MG	3600/23T	3600/23T	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)*
GEODON CAPSULE, HARD 80MG	3599/23T	3599/23T	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)*
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	1933/23T	1933/23T	SAPIENS PHARMACEUTICALS 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
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	1934/23T	1934/23T	SAPIENS PHARMACEUTICALS 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
LAVIFENT PATCH, TRANSDERMAL 25MCG/HOUR	2418/23T	2418/23T	LAVIPHARM A.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
LAVIFENT PATCH, TRANSDERMAL 100MCG/HOUR	2415/23T	2415/23T	LAVIPHARM A.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
LAVIFENT PATCH, TRANSDERMAL 75MGG/HOUR	2416/23T	2416/23T	LAVIPHARM A.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
LAVIFENT PATCH, TRANSDERMAL 50MCG/HOUR	2417/23T	2417/23T	LAVIPHARM A.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
PRODUODOPA SOLUTION FOR INFUSION (240MG+12MG)/ML	3596/23T, 3597/23T, 3598/23T	3596/23T, 3597/23T, 3598/23T	ABBVIE PHARMACEUTICALS 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 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.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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	3409/23T	3409/23T	SANOFI WINTHROP INDUSTRIE.	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 20MG(2000IU)/0.2ML	3411/23T	3411/23T	SANOFI WINTHROP INDUSTRIE.	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 40MG(4000IU)/0.4ML	3410/23T	3410/23T	SANOFI WINTHROP INDUSTRIE.	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 80MG(8000IU)/0.8ML	3408/23T	3408/23T	SANOFI WINTHROP INDUSTRIE.	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
FUGENTIN TABLET, FILM COATED 1000MG	889/23T, 890/23T	889/23T, 890/23T	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.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 C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	3140/23T, 3141/23T, 3142/23T, 3143/23T, 3144/23T, 3145/23T, 3146/23T, 3147/23T	3140/23T, 3141/23T, 3142/23T, 3143/23T, 3144/23T, 3145/23T, 3146/23T, 3147/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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 - 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 - 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, B.I.d.1.c B.I.d.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where

				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, 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 -
HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	3132/23T, 3133/23T, 3134/23T, 3135/23T, 3136/23T, 3137/23T, 3138/23T, 3139/23T	3132/23T, 3133/23T, 3134/23T, 3135/23T, 3136/23T, 3137/23T, 3138/23T, 3139/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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 - 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 - 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, B.I.d.1.c B.I.d.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage

				conditions of the active substance where 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, 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 -
STATEZOL TABLET, FILM COATED 10MG/10MG	4630/23T, 4631/23T, 4632/23T, 4633/23T	4630/23T, 4631/23T, 4632/23T, 4633/23T	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, 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.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
STATEZOL TABLET, FILM COATED 20MG/10MG	4626/23T, 4627/23T, 4628/23T, 4629/23T	4626/23T, 4627/23T, 4628/23T, 4629/23T	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, 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.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
STATEZOL TABLET, FILM COATED 5MG/10MG	4634/23T, 4635/23T, 4636/23T, 4637/23T	4634/23T, 4635/23T, 4636/23T, 4637/23T	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, 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.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
STATEZOL TABLET, FILM COATED 40MG/10MG	4622/23T, 4623/23T, 4624/23T, 4625/23T	4622/23T, 4623/23T, 4624/23T, 4625/23T	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, 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.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
TRACRIUM INJECTION 10MG/ML	2666/23T	2666/23T	ASPEN PHARMA TRADING 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
ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	1272/23T	1272/23T	ALTAN PHARMACEUTICALS 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
OPHTHA-BIOTIC EYE DROPS, SOLUTION (20MG/5MG)/ML	125/22T, 126/22T, 127/22T, 128/22T	125/22T, 126/22T, 127/22T, 128/22T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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.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.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
OPTIVATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	7329/21T	7329/21T	BPL BIOPRODUCTS LABORATORY GMBH	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
OPTIVATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	4308/22T	4308/22T	BPL BIOPRODUCTS LABORATORY GMBH	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
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	148/23T	148/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	149/23T	149/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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
STEROFUNDIN ISO SOLUTION FOR INFUSION	3730/23T	3730/23T	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
TRILEPTAL TABLET, FILM COATED 600MG	1079/23T	1079/23T	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
TRILEPTAL TABLET, FILM COATED 300MG	1080/23T	1080/23T	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
TRILEPTAL TABLET, FILM COATED 150MG	1078/23T	1078/23T	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
HYDROCORTISONE RENATA TABLET 10MG	9486/22T	9486/22T	RENATA PHARMACEUTICALS (IRELAND) LIMITED	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)
HYDROCORTISONE RENATA TABLET 20MG	9485/22T	9485/22T	RENATA PHARMACEUTICALS (IRELAND) LIMITED	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)
FLAGYL TABLET 400MG	9231/21T, 9232/21T	9231/21T, 9232/21T	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
FLAGYL TABLET 400MG	4104/21T, 4105/21T	4104/21T, 4105/21T	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
FLAGYL TABLET 400MG	2598/23T, 2599/23T	2598/23T, 2599/23T	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)* A.z A.z - ADMINISTRATIVE CHANGES - Other variation

OXYCONTIN TABLET, PROLONGED-RELEASE 5MG	3561/23T	3561/23T	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)
OXYCONTIN TABLET, PROLONGED-RELEASE 20MG	3560/23T	3560/23T	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)
OXYCONTIN TABLET, PROLONGED-RELEASE 80MG	3557/23T	3557/23T	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)
OXYCONTIN TABLET, PROLONGED-RELEASE 10MG	3559/23T	3559/23T	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)
OXYCONTIN TABLET, PROLONGED-RELEASE 40MG	3558/23T	3558/23T	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)
ZOLOFT TABLET, FILM COATED 50MG	1905/23T	1905/23T	UPJOHN HELLAS 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
ZOLOFT TABLET, FILM COATED 100MG	1904/23T	1904/23T	UPJOHN HELLAS 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
AKAMON TABLET 3MG	3788/23T	3788/23T	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
AKAMON TABLET 1.5MG	3789/23T	3789/23T	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
LETYBO POWDER FOR SOLUTION FOR INJECTION 50U	3549/23T	3549/23T	CROMA-PHARMA GMBH	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
TRAMADOL/PARACETAMOL ACCORD EFFERVESCENT TABLET 37.5MG/325MG	1414/23T	1414/23T	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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	2603/23T	2603/23T	GLAXOSMITHKLINE (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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	2602/23T	2602/23T	GLAXOSMITHKLINE (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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	2601/23T	2601/23T	GLAXOSMITHKLINE (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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	2604/23T	2604/23T	GLAXOSMITHKLINE (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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	2600/23T	2600/23T	GLAXOSMITHKLINE (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
OLANZAPINE AUROBINDO TABLET 5MG	988/23T	988/23T	AUROBINDO PHARMA (MALTA) 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/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 - Other variation
OLANZAPINE AUROBINDO TABLET 10MG	987/23T	987/23T	AUROBINDO PHARMA (MALTA) 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
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	3548/23T	3548/23T	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)*
ALBUMEON SOLUTION FOR INFUSION 200G/l	3874/23T, 3875/23T, 3876/23T,	3874/23T, 3875/23T, 3876/23T,	CSL BEHRING GMBH	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED

	3877/23T, 3878/23T	3877/23T, 3878/23T		PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process 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.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.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 ACCORD TABLET, FILM COATED 5MG	559/23T	559/23T	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)*
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	558/23T	558/23T	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)*
ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	557/23T	557/23T	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)*
ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	556/23T	556/23T	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)*
ONCOTICE POWDER FOR SOLUTION FOR INFUSION	8645/22T	8645/22T	MSD AFVEE	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
RIBAVIRIN AUROBINDO TABLET, FILM COATED 200MG	3793/23T, 3794/23T, 3795/23T	3793/23T, 3794/23T, 3795/23T	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TEGLUTIK ORAL SUSPENSION 5MG/ML	1270/23T	1270/23T	ITF 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
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 125MCG/5MCG	3006/23T	3006/23T	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	3007/23T	3007/23T	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 250MCG/10MCG	3005/23T	3005/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EZETIMIBE+SIMVASTATIN/MYLAN TABLET 10MG/20MG	4102/23T	4102/23T	MYLAN IRELAND LIMITED	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

EZETIMIBE+SIMVASTATIN/MYLAN TABLET 10MG/10MG	4100/23T	4100/23T	MYLAN IRELAND LIMITED	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
EZETIMIBE+SIMVASTATIN/MYLAN TABLET 10MG/40MG	4101/23T	4101/23T	MYLAN IRELAND LIMITED	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
NEISVAC-C SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 10MCG/0.5ML	3916/23T, 3917/23T, 3918/23T	3916/23T, 3917/23T, 3918/23T	PFIZER HELLAS AE	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.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 - Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of medicinal products B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	2614/23T, 2615/23T	2614/23T, 2615/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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.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
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	2618/23T, 2619/23T	2618/23T, 2619/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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.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
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	8766/22T	8766/22T	CSL BEHRING 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
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	3565/23T, 3566/23T, 3567/23T	3565/23T, 3566/23T, 3567/23T	OCTAPHARMA (IP) SPRL	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.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.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	3562/23T, 3563/23T, 3564/23T	3562/23T, 3563/23T, 3564/23T	OCTAPHARMA (IP) SPRL	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.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.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
APLERIA TABLET, FILM COATED 50MG	3691/23T	3691/23T	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
APLERIA TABLET, FILM COATED 25MG	3692/23T	3692/23T	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
ZITAMIN SOLUTION FOR INJECTION 7.5MG/ML	3758/23T	3758/23T	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
ZITAMIN SOLUTION FOR INFUSION 2MG/ML	3761/23T	3761/23T	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
ZITAMIN SOLUTION FOR INJECTION 10MG/ML	3757/23T	3757/23T	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
ZITAMIN SOLUTION FOR INJECTION 2MG/ML	3760/23T	3760/23T	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

ZITAMIN SOLUTION FOR INJECTION 5MG/ML	3759/23T	3759/23T	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
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	5229/22T	5229/22T	TEVA 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*
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	5228/22T	5228/22T	TEVA 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*
BORTEZOMIB/TEVA POWDER FOR SOLUTION FOR INJECTION 3.5MG/VIAL	4090/23T	4090/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BIOFLOR CAPSULE, HARD 200MG	4135/23T	4135/23T	BIOCODEX	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
ATAZANAVIR REMEDICA CAPSULE, HARD 100MG	387/23T	387/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ATAZANAVIR REMEDICA CAPSULE, HARD 150MG	386/23T	386/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ATAZANAVIR REMEDICA CAPSULE, HARD 300MG	384/23T	384/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ATAZANAVIR REMEDICA CAPSULE, HARD 200MG	385/23T	385/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	2091/23T	2091/23T	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	2090/23T	2090/23T	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	2092/23T	2092/23T	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 200MG	2089/23T	2089/23T	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

NICORETTE QUICKSPRAY OROMUCOSAL SPRAY, SOLUTION 1MG/DOSE	3726/23T	3726/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
IMODIUM PLUS TABLET 2MG/125MG	3727/23T	3727/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	3728/23T	3728/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MICROLAX RECTAL SOLUTION (0.45G/0.0645G/4.465G)/DOSE	3729/23T	3729/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MEPIDENTAL SOLUTION FOR INJECTION IN A CARTRIDGE 30MG/ML	3290/23T	3290/23T	INIBSA DENTAL S.L.U.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
PROLUTEX SOLUTION FOR INJECTION 25MG	3537/23T	3537/23T	IBSA FARMACEUTICI ITALIA SRL	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
ATORVASTATIN AUROBINDO TABLET, FILM COATED 10MG	2893/23T	2893/23T	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
ATORVASTATIN AUROBINDO TABLET, FILM COATED 20MG	2892/23T	2892/23T	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
ATORVASTATIN AUROBINDO TABLET, FILM COATED 40MG	2891/23T	2891/23T	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
GEODON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 20MG/ML	3833/22T	3833/22T	UPJOHN HELLAS LTD	B.II.a.6 B.II.a.6 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Deletion of the solvent / diluent container from the pack
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	4009/23T	4009/23T	TEVA PHARMA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	4010/23T	4010/23T	TEVA PHARMA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	4008/23T	4008/23T	TEVA PHARMA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VORICONAZOLE/ELPEN POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	3717/23T	3717/23T	ELPEN PHARMACEUTICAL CO INC	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

RIASTAP POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	3520/23T	3520/23T	CSL BEHRING GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
GLUCOPHAGE TABLET, FILM COATED 500MG	7397/22T, 7398/22T, 7399/22T	7397/22T, 7398/22T, 7399/22T	MERCK A E HELLAS	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
GLUCOPHAGE TABLET, FILM COATED 500MG	7397/22T, 7398/22T, 7399/22T	7397/22T, 7398/22T, 7399/22T	MERCK A E HELLAS	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
GLUCOPHAGE TABLET, FILM COATED 1000MG	7391/22T, 7392/22T, 7393/22T	7391/22T, 7392/22T, 7393/22T	MERCK A E HELLAS	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
GLUCOPHAGE TABLET, FILM COATED 1000MG	7391/22T, 7392/22T, 7393/22T	7391/22T, 7392/22T, 7393/22T	MERCK A E HELLAS	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
GLUCOPHAGE TABLET, FILM COATED 850MG	7394/22T, 7395/22T, 7396/22T	7394/22T, 7395/22T, 7396/22T	MERCK A E HELLAS	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
GLUCOPHAGE TABLET, FILM COATED 850MG	7394/22T, 7395/22T, 7396/22T	7394/22T, 7395/22T, 7396/22T	MERCK A E HELLAS	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
HUMULIN REGULAR SOLUTION FOR INJECTION IN A CARTRIDGE 100IU/ML	7564/22T, 7565/22T, 7566/22T, 7567/22T	7564/22T, 7565/22T, 7566/22T, 7567/22T	PHADISCO 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.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.c B.I.d.1.c - 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 ap 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
HUMULIN M3 SUSPENSION FOR INJECTION IN CARTRIDGE 100IU/ML	7560/22T, 7561/22T, 7562/22T, 7563/22T	7560/22T, 7561/22T, 7562/22T, 7563/22T	PHADISCO 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.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.c B.I.d.1.c - 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 ap 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
HUMULIN NPH SUSPENSION FOR INJECTION IN CARTRIDGE 100IU/ML	7556/22T, 7557/22T, 7558/22T, 7559/22T	7556/22T, 7557/22T, 7558/22T, 7559/22T	PHADISCO 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.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.c B.I.d.1.c - 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 ap 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
METHOTREXATE ACCORD SOLUTION FOR INJECTION 25MG/ML	422/23T	422/23T	ACCORD HEALTHCARE S.L.U	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
VERTIGO-N TABLET 20MG/40MG	1368/22T	1368/22T	GALENICA 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
OCTISET VAGINAL SOLUTION	1274/23T	1274/23T	T.C.CHRISTOFOROU 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
OCTISET CUTANEOUS SOLUTION	1273/23T	1273/23T	T.C.CHRISTOFOROU 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
AMLODIPIN ACCORD TABLET 5MG	3589/23T	3589/23T	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
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML PFS	3516/23T	3516/23T	IBSA FARMACEUTICI ITALIA SRL	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
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML PFS	3517/23T	3517/23T	IBSA FARMACEUTICI ITALIA SRL	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
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/VIAL	3519/23T	3519/23T	IBSA FARMACEUTICI ITALIA SRL	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
MERIOFERT PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 900IU/VIAL	3515/23T	3515/23T	IBSA FARMACEUTICI ITALIA SRL	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
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/VIAL	3518/23T	3518/23T	IBSA FARMACEUTICI ITALIA SRL	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
CISATRACURIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	3324/23T	3324/23T	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
CISATRACURIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	3323/23T	3323/23T	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
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML PFS	1969/23T, 1970/23T, 1971/23T, 1972/23T, 1973/23T, 1974/23T	1969/23T, 1970/23T, 1971/23T, 1972/23T, 1973/23T, 1974/23T	IBSA FARMACEUTICI ITALIA SRL	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
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/VIAL	1987/23T, 1988/23T, 1989/23T, 1990/23T, 1991/23T, 1992/23T	1987/23T, 1988/23T, 1989/23T, 1990/23T, 1991/23T, 1992/23T	IBSA FARMACEUTICI ITALIA SRL	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
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/VIAL	1981/23T, 1982/23T, 1983/23T, 1984/23T, 1985/23T, 1986/23T	1981/23T, 1982/23T, 1983/23T, 1984/23T, 1985/23T, 1986/23T	IBSA FARMACEUTICI ITALIA SRL	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
MERIOFERT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML PFS	1975/23T, 1976/23T, 1977/23T, 1978/23T, 1979/23T, 1980/23T	1975/23T, 1976/23T, 1977/23T, 1978/23T, 1979/23T, 1980/23T	IBSA FARMACEUTICI ITALIA SRL	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
SYMBICORT PRESSURISED INHALATION, SUSPENSION 160/4.5MCG/ACTUATION	9195/22T	9195/22T	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 PRESSURISED INHALATION, SUSPENSION 80MCG/2.25MCG/ACTUATION	9194/22T	9194/22T	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
HEXAFLU DAY & NIGHT TABLET 500MG/60MG AND 500MG/25MG	3321/22T, 3322/22T	3321/22T, 3322/22T	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
ATODEL TABLET 2MG	2568/23T, 2569/23T, 2570/23T	2568/23T, 2569/23T, 2570/23T	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.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
ATODEL TABLET 5MG	2565/23T, 2566/23T, 2567/23T	2565/23T, 2566/23T, 2567/23T	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.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
ATODEL TABLET 1MG	2571/23T, 2572/23T, 2573/23T	2571/23T, 2572/23T, 2573/23T	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.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
OCTORET SOLUTION FOR INJECTION OR INFUSION 40MG/ML	4025/23T	4025/23T	NORIDEM ENTERPRISES 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
OCTORET SOLUTION FOR INJECTION OR INFUSION 20MG/ML	4026/23T	4026/23T	NORIDEM ENTERPRISES 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
OCTORET SOLUTION FOR INJECTION OR INFUSION 80MG/ML	4024/23T	4024/23T	NORIDEM ENTERPRISES 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
CALCIUM-SANDOZ FORTE EFFERVESCENT TABLET 500MG	3009/23T	3009/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	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
COVERSYL TABLET, FILM COATED 5MG	9042/20T	9042/20T	LES LABORATOIRES SERVIER	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
COVERSYL TABLET, FILM COATED 2.5MG	9043/20T	9043/20T	LES LABORATOIRES SERVIER	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
COVERSYL TABLET, FILM COATED 10MG	9041/20T	9041/20T	LES LABORATOIRES SERVIER	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
NORMOSANG CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	5336/22T, 5337/22T	5336/22T, 5337/22T	ORPHAN EUROPE SARL, FRANCE	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.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)
EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	515/23T, 516/23T, 517/23T, 518/23T	515/23T, 516/23T, 517/23T, 518/23T	SANOFI PASTEUR.	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.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
ABACAVIR ACCORD TABLET, FILM COATED 300MG	1495/23T	1495/23T	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
COVERSYL TABLET, FILM COATED 10MG	7072/21T	7072/21T	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
COVERSYL TABLET, FILM COATED 2.5MG	7070/21T	7070/21T	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
COVERSYL TABLET, FILM COATED 5MG	7071/21T	7071/21T	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
CLAVOMID TABLET, FILM COATED 375MG	1365/23T	1365/23T	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
CLAVOMID TABLET, FILM COATED 625MG	1366/23T	1366/23T	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
ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	4002/23T	4002/23T	SANDOZ 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
ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	4001/23T	4001/23T	SANDOZ 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
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	4003/23T	4003/23T	SANDOZ 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
ATORVASTATIN GENERICS TABLET, FILM COATED 20MG	3715/23T	3715/23T	GENERICS PHARMA HELLAS 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 GENERICS TABLET, FILM COATED 10MG	3716/23T	3716/23T	GENERICS PHARMA HELLAS 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 GENERICS TABLET, FILM COATED 40MG	3714/23T	3714/23T	GENERICS PHARMA HELLAS 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
LOMEXIN VAGINAL CAPSULE, SOFT 600MG	9372/22T	9372/22T	RECORDATI IRELAND LTD	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

SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/500MG	2910/23T, 2911/23T, 2912/23T, 2913/23T	2910/23T, 2911/23T, 2912/23T, 2913/23T	APC INSTYTUT SP. Z.O.O.	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
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/1000MG	2906/23T, 2907/23T, 2908/23T, 2909/23T	2906/23T, 2907/23T, 2908/23T, 2909/23T	APC INSTYTUT SP. Z.O.O.	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
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 100MG/1000MG	2902/23T, 2903/23T, 2904/23T, 2905/23T	2902/23T, 2903/23T, 2904/23T, 2905/23T	APC INSTYTUT SP. Z.O.O.	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
LENALIDOMIDE NORAMEDA CAPSULE, HARD 10MG	2409/23T	2409/23T	UAB NORAMEDA	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
LENALIDOMIDE NORAMEDA CAPSULE, HARD 5MG	2410/23T	2410/23T	UAB NORAMEDA	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
LENALIDOMIDE NORAMEDA CAPSULE, HARD 25MG	2407/23T	2407/23T	UAB NORAMEDA	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
LENALIDOMIDE NORAMEDA CAPSULE, HARD 15MG	2408/23T	2408/23T	UAB NORAMEDA	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
EFAVIRENZ AUROBINDO TABLET, FILM COATED 600MG	3085/23T	3085/23T	AUROBINDO PHARMA (MALTA) 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)*
FOSTER INHALATION SOLUTION, PRESSURISED (200MCG/6MCG)/ACTUATION	2399/23T, 2400/23T	2399/23T, 2400/23T	CHIESI FARMACEUTICI SPA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.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
SIRODROL ORAL SOLUTION 10MG/ML	3367/21T	3367/21T	VIANEX 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
LANOXIN PG TABLET 0.0625MG	3366/23T	3366/23T	ASPEN PHARMA TRADING LIMITED	C.I.z C.I.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
RABEPRAZOLE KRKA TABLET, GASTRO-RESISTANT 20MG	7827/22T	7827/22T	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
RABEPRAZOLE KRKA TABLET, GASTRO-RESISTANT 10MG	7828/22T	7828/22T	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
AMOXAPEN CAPSULE, HARD 250MG	8009/22T, 8010/22T, 8011/22T, 8012/22T, 8013/22T, 8014/22T, 8015/22T, 8016/22T, 8017/22T, 8018/22T, 8019/22T, 8020/22T, 8021/22T, 8022/22T, 8023/22T, 8024/22T, 8025/22T, 8026/22T, 8027/22T, 8028/22T, 8029/22T, 8030/22T, 8031/22T, 8032/22T, 8033/22T, 8034/22T, 8035/22T, 8036/22T	8009/22T, 8010/22T, 8011/22T, 8012/22T, 8013/22T, 8014/22T, 8015/22T, 8016/22T, 8017/22T, 8018/22T, 8019/22T, 8020/22T, 8021/22T, 8022/22T, 8023/22T, 8024/22T, 8025/22T, 8026/22T, 8027/22T, 8028/22T, 8029/22T, 8030/22T, 8031/22T, 8032/22T, 8033/22T, 8034/22T, 8035/22T, 8036/22T	REMEDICA LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANG B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - B.II.a.3.b.5 B.II.a.3.b.5 - QUALITY CHANG B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - B.II.d.z B.II.d.z - QUALITY CHANGES - FIN B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - B.II.d.1.a B.II.d.1.a - QUALITY CHANGES -

				B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - A B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - A B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - A B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANG B.II.e.5.b B.II.e.5.b - QUALITY CHANGES -
AMOXAPEN CAPSULE, HARD 500MG	7979/22T, 7980/22T, 7981/22T, 7982/22T, 7983/22T, 7984/22T, 7985/22T, 7986/22T, 7987/22T, 7988/22T, 7989/22T, 7990/22T, 7991/22T, 7992/22T, 7993/22T, 7994/22T, 7995/22T, 7996/22T, 7997/22T, 7998/22T, 7999/22T, 8000/22T, 8001/22T, 8002/22T, 8003/22T, 8004/22T, 8005/22T, 8006/22T, 8007/22T, 8008/22T	7979/22T, 7980/22T, 7981/22T, 7982/22T, 7983/22T, 7984/22T, 7985/22T, 7986/22T, 7987/22T, 7988/22T, 7989/22T, 7990/22T, 7991/22T, 7992/22T, 7993/22T, 7994/22T, 7995/22T, 7996/22T, 7997/22T, 7998/22T, 7999/22T, 8000/22T, 8001/22T, 8002/22T, 8003/22T, 8004/22T, 8005/22T, 8006/22T, 8007/22T, 8008/22T	REMEDICA LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANG B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - B.II.a.3.b.5 B.II.a.3.b.5 - QUALITY CHANG B.II.d.2.z B.II.d.2.z - QUALITY CHANGES - B.II.d.z B.II.d.z - QUALITY CHANGES - FIN B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - B.II.d.1.c B.II.d.1.c

				- QUALITY CHANGES - B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - A B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - A B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - A B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANG B.II.e.5.b B.II.e.5.b - QUALITY CHANGES -
AMOXAPEN CAPSULE, HARD 250MG	7772/22T	7772/22T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
AMOXAPEN CAPSULE, HARD 500MG	7771/22T	7771/22T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
METFORMIN ACCORD TABLET, FILM COATED 850MG	5122/22T	5122/22T	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
METFORMIN ACCORD TABLET, FILM COATED 500MG	5121/22T	5121/22T	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
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 40MG	610/23T	610/23T	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
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 10MG	612/23T	612/23T	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
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 20MG	611/23T	611/23T	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
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 5MG	613/23T	613/23T	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
AGREGEX TABLET, FILM COATED 75MG	4353/23T	4353/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AXETINE TABLET, FILM COATED 250MG	3317/23T	3317/23T	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
AXETINE TABLET, FILM COATED 500MG	3316/23T	3316/23T	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
OLIMEL N9E EMULSION FOR INFUSION	3435/23T	3435/23T	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	3433/23T	3433/23T	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	3434/23T	3434/23T	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	3432/23T	3432/23T	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	3436/23T	3436/23T	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	3437/23T	3437/23T	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
SEPTANEST SOLUTION FOR INJECTION (40MG/5MCG)/ML	3613/23T	3613/23T	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	3612/23T	3612/23T	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
QUETIAPINE/GENERICS TABLET, FILM COATED 25MG	8312/21T	8312/21T	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of

				the medicinal product - for Nationally Authorised Products
QUETIAPINE/GENERICS TABLET, FILM COATED 100MG	8310/21T	8310/21T	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
QUETIAPINE/GENERICS TABLET, FILM COATED 200MG	8311/21T	8311/21T	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
QUETIAPINE/GENERICS TABLET, FILM COATED 25MG	278/22T, 279/22T, 280/22T	278/22T, 279/22T, 280/22T	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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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)*
QUETIAPINE/GENERICS TABLET, FILM COATED 100MG	281/22T, 282/22T, 283/22T	281/22T, 282/22T, 283/22T	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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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)*
QUETIAPINE/GENERICS TABLET, FILM COATED 200MG	284/22T, 285/22T, 286/22T	284/22T, 285/22T, 286/22T	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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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)*
QUETIAPINE/GENERICS TABLET, FILM COATED 25MG	747/21T	747/21T	MYLAN IRELAND 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
QUETIAPINE/GENERICS TABLET, FILM COATED 100MG	748/21T	748/21T	MYLAN IRELAND 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
QUETIAPINE/GENERICS TABLET, FILM COATED 200MG	749/21T	749/21T	MYLAN IRELAND 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
QUETIAPINE/GENERICS TABLET, FILM COATED 25MG	5058/21T	5058/21T	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
QUETIAPINE/GENERICS TABLET, FILM COATED 200MG	5057/21T	5057/21T	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
QUETIAPINE/GENERICS TABLET, FILM COATED 100MG	5056/21T	5056/21T	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
QUETIAPINE/GENERICS TABLET, FILM COATED 25MG	9231/22T	9231/22T	MYLAN IRELAND 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
QUETIAPINE/GENERICS TABLET, FILM COATED 200MG	9229/22T	9229/22T	MYLAN IRELAND 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
QUETIAPINE/GENERICS TABLET, FILM COATED 100MG	9230/22T	9230/22T	MYLAN IRELAND 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
LOSARTAN AUROBINDO TABLET, FILM COATED 50MG	3329/23T, 3330/23T	3329/23T, 3330/23T	AUROBINDO PHARMA (MALTA) 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
LOSARTAN AUROBINDO TABLET, FILM COATED 50MG	9732/22T, 9733/22T	9732/22T, 9733/22T	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)
FOSTER INHALATION SOLUTION, PRESSURISED 100/6 MCG/ACTUATION	2411/23T, 2412/23T	2411/23T, 2412/23T	CHIESI FARMACEUTICI SPA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.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
LOTEMAX EYE DROPS 0.5%	2678/23T	2678/23T	DR.GERHARD MANN CHEM.-PHARM. FABRIK 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
VENLAXIN TABLET, PROLONGED-RELEASE 225MG	4276/23T	4276/23T	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 - Other changes
VENLAXIN TABLET, PROLONGED-RELEASE 150MG	4277/23T	4277/23T	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 - Other changes
VENLAXIN TABLET, PROLONGED-RELEASE 75MG	4278/23T	4278/23T	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 - Other changes
SIRANALEN CAPSULE, HARD 75MG	690/23T, 691/23T, 692/23T	690/23T, 691/23T, 692/23T	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
SIRANALEN CAPSULE, HARD 150MG	687/23T, 688/23T, 689/23T	687/23T, 688/23T, 689/23T	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
SIRANALEN CAPSULE, HARD 300MG	684/23T, 685/23T, 686/23T	684/23T, 685/23T, 686/23T	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
NOLVADEX-D TABLET, FILM COATED 20MG	3980/23T	3980/23T	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
NOLVADEX TABLET, FILM COATED 10MG	3979/23T	3979/23T	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
LAMISIL TABLET 250MG	1140/23T, 1141/23T, 1142/23T, 1143/23T, 1144/23T	1140/23T, 1141/23T, 1142/23T, 1143/23T, 1144/23T	NOVARTIS IRELAND 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 th 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.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 r 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
LAMISIL TABLET 125MG	1145/23T, 1146/23T, 1147/23T, 1148/23T, 1149/23T	1145/23T, 1146/23T, 1147/23T, 1148/23T, 1149/23T	NOVARTIS IRELAND 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 th 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.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 r 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
PANADOL COLD & FLU & COUGH CAPSULE, HARD 500MG/100MG/6.1MG	3299/23T	3299/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	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
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	3530/23T	3530/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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)
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	3499/23T, 3500/23T, 3501/23T, 3502/23T, 3503/23T, 3504/23T, 3505/23T, 3506/23T	3499/23T, 3500/23T, 3501/23T, 3502/23T, 3503/23T, 3504/23T, 3505/23T, 3506/23T	IBSA FARMACEUTICI ITALIA SRL	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.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 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 informat
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	3483/23T, 3484/23T, 3485/23T, 3486/23T, 3487/23T, 3488/23T, 3489/23T, 3490/23T	3483/23T, 3484/23T, 3485/23T, 3486/23T, 3487/23T, 3488/23T, 3489/23T, 3490/23T	IBSA FARMACEUTICI ITALIA SRL	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.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 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 informat
FOSTIMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 150IU/ML	3507/23T, 3508/23T, 3509/23T, 3510/23T, 3511/23T, 3512/23T, 3513/23T, 3514/23T	3507/23T, 3508/23T, 3509/23T, 3510/23T, 3511/23T, 3512/23T, 3513/23T, 3514/23T	IBSA FARMACEUTICI ITALIA SRL	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.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 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 informat
FOSTIMON PFS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 75IU/ML	3491/23T, 3492/23T, 3493/23T, 3494/23T, 3495/23T, 3496/23T, 3497/23T, 3498/23T	3491/23T, 3492/23T, 3493/23T, 3494/23T, 3495/23T, 3496/23T, 3497/23T, 3498/23T	IBSA FARMACEUTICI ITALIA SRL	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.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 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 informat
APO-GO PEN SOLUTION FOR INJECTION 10MG/ML	4027/23T	4027/23T	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
VOLTAREN EMUGEL GEL 1%	3259/23T	3259/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	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
ARTEPRO TABLET, FILM COATED 10MG	3257/23T	3257/23T	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
ARTEPRO TABLET, FILM COATED 40MG	3255/23T	3255/23T	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
ARTEPRO TABLET, FILM COATED 5MG	3258/23T	3258/23T	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
ARTEPRO TABLET, FILM COATED 20MG	3256/23T	3256/23T	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
SUGAMMADEX ANABIOSIS SOLUTION FOR INJECTION 100MG/ML	3365/23T	3365/23T	ANABIOSIS PC.	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

VENLAXIN TABLET, PROLONGED-RELEASE 225MG	3952/23T	3952/23T	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
VENLAXIN TABLET, PROLONGED-RELEASE 150MG	3953/23T	3953/23T	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
VENLAXIN TABLET, PROLONGED-RELEASE 75MG	3954/23T	3954/23T	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
ISOPTO-MAXITROL EYE OINTMENT	2056/23T	2056/23T	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
GEMNIL POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	3253/23T, 3254/23T	3253/23T, 3254/23T	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
GEMNIL POWDER FOR SOLUTION FOR INFUSION 1000MG/VIAL	3251/23T, 3252/23T	3251/23T, 3252/23T	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
TICOVAC JUNIOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.25ML/DOSE	546/23T	546/23T	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 - Other changes
TICOVAC SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.5ML/DOSE	545/23T	545/23T	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 - Other changes
NICORETTE QUICKSPRAY OROMUCOSAL SPRAY, SOLUTION 1MG/DOSE	2221/23T	2221/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BENYLIN MUCUS COUGH WARM HONEY & LEMON FLAVOUR SYRUP 20MG/ML	2222/23T	2222/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	2223/23T	2223/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
IMODIUM PLUS TABLET 2MG/125MG	2220/23T	2220/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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	3123/23T, 3124/23T	3123/23T, 3124/23T	GE HEALTHCARE AS	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 with its corresponding test method
VAXIGRIPTETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	7903/22T, 7904/22T, 7905/22T	7903/22T, 7904/22T, 7905/22T	SANOFI PASTEUR.	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. C 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/immunol ogical substance, which may have a significa
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	3075/23T, 3076/23T, 3077/23T, 3078/23T	3075/23T, 3076/23T, 3077/23T, 3078/23T	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.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.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 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
DALTEX TABLET, FILM COATED 50MG/850MG	3328/23T	3328/23T	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)
DALTEX TABLET, FILM COATED 50MG/1000MG	3327/23T	3327/23T	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)

OPTIVATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	3086/23T	3086/23T	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
PANADOL COLD AND FLU TABLET, FILM COATED	1880/23T	1880/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZOVIDUO CREAM (50MG/10MG)/G	1881/23T	1881/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DICLODUO COMBI MODIFIED-RELEASE CAPSULE, HARD	1951/23T	1951/23T	PHARMASWISS CESKA REPUBLIKA SRO	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
IMOVANE TABLET, FILM COATED 7.5MG	7929/22T	7929/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AFLUON EYE DROPS, SOLUTION 0.05%	7931/22T	7931/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
NOVANTRONE CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/ML	7934/22T	7934/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MOLAXOLE POWDER FOR ORAL SOLUTION	7930/22T	7930/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ACNATAC GEL	7932/22T	7932/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BILENI NASAL SPRAY, SUSPENSION	7935/22T	7935/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DYMISTA NASAL SPRAY, SUSPENSION	7936/22T	7936/22T	MEDA PHARMACEUTICALS S.A.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ELIDEL CREAM 1%	7933/22T	7933/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	320/23T	320/23T	TEVA GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DEMOLOX POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG/VIAL	3732/23T, 3733/23T, 3734/23T	3732/23T, 3733/23T, 3734/23T	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 B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
SIRODROL ORAL SOLUTION 10MG/ML	3307/23T, 3308/23T	3307/23T, 3308/23T	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.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
ZEPILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	514/23T	514/23T	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
ZEPILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	513/23T	513/23T	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
DOVOBET OINTMENT	3880/22T	3880/22T	LEO PHARMA A/S	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
VALGANCICLOVIR AUROBINDO TABLET, FILM COATED 450MG	3079/23T	3079/23T	AUROBINDO PHARMA (MALTA) 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)*
EZETIMIBE/MYLAN TABLET 10MG	2158/23T	2158/23T	MYLAN PHARMACEUTICALS LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
BOSENTAN AUROBINDO TABLET, FILM COATED 125MG	3068/23T, 3069/23T	3068/23T, 3069/23T	AUROBINDO PHARMA (MALTA) 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.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
BOSENTAN AUROBINDO TABLET, FILM COATED 62.5MG	3070/23T, 3071/23T	3070/23T, 3071/23T	AUROBINDO PHARMA (MALTA) 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.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
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/25MG	9462/22T	9462/22T	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
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/25MG	9460/22T	9460/22T	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
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/12.5MG	9463/22T	9463/22T	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

OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/12.5MG	9461/22T	9461/22T	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
AMOXIL FORTE POWDER FOR ORAL SUSPENSION 250MG/5ML	861/23T	861/23T	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 product - Change outside the approved specifications limits range
PICOPREP POWDER FOR ORAL SOLUTION	null	null	FERRING HELLAS MEPE	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.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
PICOPREP POWDER FOR ORAL SOLUTION	null	null	FERRING HELLAS MEPE	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.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
ZOVIDUO CREAM (50MG/10MG)/G	1879/23T	1879/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	1878/23T	1878/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TESTOGEL TRANSDERMAL GEL 16.2 MG/G	8174/22T	8174/22T	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/intermediate used in the manufacturing process of 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	2204/23T, 2205/23T, 2206/23T, 2207/23T	2204/23T, 2205/23T, 2206/23T, 2207/23T	BAXTER (HELLAS) EPE	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.c.2.b B.II.c.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Deletion of a test procedure if an alternative test procedure is alread A.7 A.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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/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
OLIMEL N7 EMULSION FOR INFUSION	2188/23T, 2189/23T, 2190/23T, 2191/23T	2188/23T, 2189/23T, 2190/23T, 2191/23T	BAXTER (HELLAS) EPE	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.c.2.b B.II.c.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Deletion of a test procedure if an alternative test procedure is alread A.7 A.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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/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
OLIMEL N12E EMULSION FOR INFUSION	2192/23T, 2193/23T, 2194/23T, 2195/23T	2192/23T, 2193/23T, 2194/23T, 2195/23T	BAXTER (HELLAS) EPE	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.c.2.b B.II.c.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Deletion of a test procedure if an alternative test procedure is alread A.7 A.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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/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
OLIMEL N9 EMULSION FOR INFUSION	2184/23T, 2185/23T, 2186/23T, 2187/23T	2184/23T, 2185/23T, 2186/23T, 2187/23T	BAXTER (HELLAS) EPE	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.c.2.b B.II.c.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Deletion of a test procedure if an alternative test procedure is alread A.7 A.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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/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
OLIMEL N7E EMULSION FOR INFUSION	2200/23T, 2201/23T, 2202/23T, 2203/23T	2200/23T, 2201/23T, 2202/23T, 2203/23T	BAXTER (HELLAS) EPE	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.c.2.b B.II.c.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Deletion of a test procedure if an alternative test procedure is alread A.7 A.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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/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
OLIMEL N9E EMULSION FOR INFUSION	2196/23T, 2197/23T, 2198/23T, 2199/23T	2196/23T, 2197/23T, 2198/23T, 2199/23T	BAXTER (HELLAS) EPE	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.c.2.b B.II.c.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Deletion of a test procedure if an alternative test procedure is alread A.7 A.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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/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
ZOVIDUO CREAM (50MG/10MG)/G	3326/23T	3326/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	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
SPORAL CAPSULE, HARD 100MG	3872/23T, 3873/23T	3872/23T, 3873/23T	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
VIDELMET TABLET, FILM COATED 50MG/850MG	3288/23T	3288/23T	DELORBIS PHARMACEUTICALS 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
VIDELMET TABLET, FILM COATED 50MG/1000MG	3287/23T	3287/23T	DELORBIS PHARMACEUTICALS 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
REGAINE MEN'S FOAM CUTANEOUS FOAM 5% W/W	8346/22T	8346/22T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
INTRATECT SOLUTION FOR INFUSION 50G/L	1150/23T	1150/23T	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
INTRATECT SOLUTION FOR INFUSION 50G/L	2557/23T	2557/23T	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
INTRATECT SOLUTION FOR INFUSION 100G/L	2556/23T	2556/23T	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

TACROLIMUS ACCORD OINTMENT 0.1%	2825/23T, 2826/23T, 2827/23T, 2828/23T, 2829/23T	2825/23T, 2826/23T, 2827/23T, 2828/23T, 2829/23T	ACCORD HEALTHCARE S.L.U	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 B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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	2484/23T	2484/23T	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
MEDOTIS TABLET, GASTRO-RESISTANT 10MG	6252/22T	6252/22T	ZENTIVA K.S.	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*
MEDOTIS TABLET, GASTRO-RESISTANT 20MG	6251/22T	6251/22T	ZENTIVA K.S.	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*
FINASTERID AUROBINDO TABLET, FILM COATED 5MG	3156/23T	3156/23T	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
RIDOCA CAPSULE, HARD 180MG	2394/23T	2394/23T	AENORASIS SA	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
RIDOCA CAPSULE, HARD 5MG	2398/23T	2398/23T	AENORASIS SA	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

RIDOCA CAPSULE, HARD 140MG	2395/23T	2395/23T	AENORASIS SA	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
RIDOCA CAPSULE, HARD 20MG	2397/23T	2397/23T	AENORASIS SA	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
RIDOCA CAPSULE, HARD 250MG	2393/23T	2393/23T	AENORASIS SA	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
RIDOCA CAPSULE, HARD 100MG	2396/23T	2396/23T	AENORASIS SA	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
RIDOCA CAPSULE, HARD 180MG	2817/23T	2817/23T	AENORASIS 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
RIDOCA CAPSULE, HARD 5MG	2821/23T	2821/23T	AENORASIS 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
RIDOCA CAPSULE, HARD 140MG	2818/23T	2818/23T	AENORASIS 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
RIDOCA CAPSULE, HARD 20MG	2820/23T	2820/23T	AENORASIS 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
RIDOCA CAPSULE, HARD 250MG	2816/23T	2816/23T	AENORASIS 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
RIDOCA CAPSULE, HARD 100MG	2819/23T	2819/23T	AENORASIS 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
CANDESARTAN KRKA TABLET 16MG	2675/23T	2675/23T	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	2677/23T	2677/23T	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	2676/23T	2676/23T	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	2674/23T	2674/23T	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
KORANDIL TABLET 10MG	3689/23T	3689/23T	REMEDICA 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
KORANDIL TABLET 5MG	3690/23T	3690/23T	REMEDICA 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
KORANDIL TABLET 20MG	3688/23T	3688/23T	REMEDICA 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
TANAFRA EYE DROPS, SOLUTION 50MCG/ML	3080/23T	3080/23T	PHARMATHEN 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
AZACITIDINE/SANDOZ POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	1759/23T	1759/23T	SANDOZ PHARMACEUTICALS D.D.	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	7046/22T	7046/22T	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

BIPHOZYL SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 22MMOL/L	1460/23T, 1461/23T, 1462/23T, 1463/23T	1460/23T, 1461/23T, 1462/23T, 1463/23T	BAXTER HOLDING 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)
MYCOPHENOLATE MOFETIL ACCORD CAPSULE, HARD 250MG	8827/20T	8827/20T	ACCORD HEALTHCARE S.L.U	B.II.b.1 a) Secondary packaging site
SYNTOCLAV TABLET, FILM COATED 625MG	3711/23T	3711/23T	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
SYNTOCLAV TABLET, FILM COATED 375MG	3712/23T	3712/23T	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
MOXICLAV TABLET, FILM COATED 1G	3572/23T	3572/23T	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
MOXICLAV TABLET, FILM COATED 625MG	3573/23T	3573/23T	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
MOXICLAV TABLET, FILM COATED 375MG	3574/23T	3574/23T	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
MOXICLAV POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/200MG	null	null	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
FLUOXETINE AUROBINDO CAPSULE, HARD 20MG	3267/23T, 3268/23T	3267/23T, 3268/23T	AUROBINDO PHARMA (MALTA) 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
CIPROXIN TABLET, FILM COATED 500MG	9071/22T	9071/22T	BAYER HELLAS ABEE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BRUFEDOL TABLET, FILM COATED 600MG	8382/22T	8382/22T	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
BRUFEDOL TABLET, FILM COATED 400MG	8383/22T	8383/22T	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
BRUFEDOL TABLET, FILM COATED 200MG	8385/22T	8385/22T	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
BRUFEDOL TABLET, PROLONGED-RELEASE 800MG	8384/22T	8384/22T	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
KABIVIT ORAL DROPS SOLUTION 14.400 IU/ML	1226/23T	1226/23T	FRESENIUS KABI HELLAS AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

KABIVIT ORAL DROPS SOLUTION 14.400 IU/ML	6037/22T	6037/22T	FRESENIUS KABI HELLAS AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BETAHISTINE AUROBINDO TABLET 8MG	668/23T	668/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
COZAAR TABLET, FILM COATED 50MG	3272/23T	3272/23T	N.V. ORGANON	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
LIPTRUZET TABLET, FILM COATED 10MG/40MG	2213/23T, 2214/23T	2213/23T, 2214/23T	N.V. ORGANON	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.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	2215/23T, 2216/23T	2215/23T, 2216/23T	N.V. ORGANON	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.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	2211/23T, 2212/23T	2211/23T, 2212/23T	N.V. ORGANON	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.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	2217/23T, 2218/23T	2217/23T, 2218/23T	N.V. ORGANON	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.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
ATORVASTATIN KRKA TABLET, FILM COATED 60MG	2755/23T	2755/23T	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

ATORVASTATIN KRKA TABLET, FILM COATED 80MG	2754/23T	2754/23T	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
ATORVASTATIN KRKA TABLET, FILM COATED 20MG	2758/23T	2758/23T	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
ATORVASTATIN KRKA TABLET, FILM COATED 10MG	2759/23T	2759/23T	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
ATORVASTATIN KRKA TABLET, FILM COATED 40MG	2756/23T	2756/23T	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
ATORVASTATIN KRKA TABLET, FILM COATED 30MG	2757/23T	2757/23T	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
HYDROCORTISONE RENATA TABLET 10MG	1108/23T	1108/23T	RENATA PHARMACEUTICALS (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)
HYDROCORTISONE RENATA TABLET 20MG	1107/23T	1107/23T	RENATA PHARMACEUTICALS (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)
DAREQ TABLET, FILM COATED 5MG	4019/23T	4019/23T	DELORBIS PHARMACEUTICALS LTD	C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in the legal status of a medicinal product for centrally authorised

				products - Other variation
IMMUNATE 250 IU FVIII/190 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250IU/5ML	2671/23T, 2672/23T	2671/23T, 2672/23T	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 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
IMMUNATE 1000 IU FVIII/750 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/10ML	2667/23T, 2668/23T	2667/23T, 2668/23T	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 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
IMMUNATE 500 IU FVIII/375 IU VWF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/5ML	2669/23T, 2670/23T	2669/23T, 2670/23T	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 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
XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	1837/23T	1837/23T	MERZ PHARMACEUTICALS GMBH	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
XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	1836/23T	1836/23T	MERZ PHARMACEUTICALS GMBH	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
EZETIMIBE/SIMVASTATIN ACCORD TABLET 10MG/10MG	3250/23T	3250/23T	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

EZETIMIBE/SIMVASTATIN ACCORD TABLET 10MG/20MG	3249/23T	3249/23T	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
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (2G/0.25G)/VIAL	1389/23T	1389/23T	MYLAN 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
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION/INFUSION (4G/0.5G)/VIAL	1388/23T	1388/23T	MYLAN 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
AFEKSIN SOLUBLE TABLET 20MG	2086/23T	2086/23T	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)*
ELOMEN SOLUTION FOR INFUSION (10MG/3MG)/ML	8478/22T	8478/22T	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 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
SELGAMIS CREAM 50MCG/G	1284/23T, 1285/23T	1284/23T, 1285/23T	GALDERMA INTERNATIONAL ,FRANCE	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.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)
AFEKSIN SOLUBLE TABLET 20MG	1288/23T	1288/23T	TEVA BV	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)
DIAZEPAM ACCORD TABLET 10MG	8363/22T	8363/22T	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	8364/22T	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
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	11/23T	11/23T	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
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	10/23T	10/23T	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
ZYVOXID SOLUTION FOR INFUSION 2MG/ML	7328/22T	7328/22T	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 - Minor change in the manufacturing process of a sterile finished product after the primary packaging step
ACICLOVIR ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	7923/22T, 7924/22T	7923/22T, 7924/22T	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 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
BENDAMUSTINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	6939/22T	6939/22T	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 finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes
SUNITINIB PHARMASCIENCE CAPSULE, HARD 37.5MG	5071/22T	5071/22T	PHARMASCIENCE INTERNATIONAL LTD	B.I.d.1.b B.I.d.1.b - 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 - Change in storage conditions of the reference standard. The same principles will apply

				as outlined for the active substance.
SUNITINIB PHARMASCIENCE CAPSULE, HARD 25MG	5072/22T	5072/22T	PHARMASCIENCE INTERNATIONAL LTD	B.I.d.1.b B.I.d.1.b - 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 - Change in storage conditions of the reference standard. The same principles will apply as outlined for the active substance.
SUNITINIB PHARMASCIENCE CAPSULE, HARD 12.5MG	5073/22T	5073/22T	PHARMASCIENCE INTERNATIONAL LTD	B.I.d.1.b B.I.d.1.b - 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 - Change in storage conditions of the reference standard. The same principles will apply as outlined for the active substance.
SUNITINIB PHARMASCIENCE CAPSULE, HARD 50MG	5070/22T	5070/22T	PHARMASCIENCE INTERNATIONAL LTD	B.I.d.1.b B.I.d.1.b - 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 - Change in storage conditions of the

				reference standard. The same principles will apply as outlined for the active substance.
CIPRALEX TABLET, FILM COATED 5MG	2133/23T	2133/23T	H.LUNDBECK A/S	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
CIPRALEX TABLET, FILM COATED 10MG	2134/23T	2134/23T	H.LUNDBECK A/S	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
CIPRALEX TABLET, FILM COATED 20MG	2135/23T	2135/23T	H.LUNDBECK A/S	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
CIPRALEX TABLET, FILM COATED 15MG	2132/23T	2132/23T	H.LUNDBECK A/S	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
AMIODARONE AUROBINDO TABLET 200MG	2085/23T	2085/23T	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
CISATRACURIUM ACCORDPHARMA SOLUTION FOR INJECTION OR INFUSION 2MG/ML	2027/23T	2027/23T	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
CISATRACURIUM ACCORDPHARMA SOLUTION FOR INJECTION OR INFUSION 2MG/ML	2025/23T, 2026/23T	2025/23T, 2026/23T	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
ZINNAT TABLET, FILM COATED 250MG	1549/23T	1549/23T	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	1548/23T	1548/23T	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	1550/23T	1550/23T	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
UNIDROPS EYE DROPS, SOLUTION 20MG/ML	909/23T	909/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES 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
UNIDROPS EYE DROPS, SOLUTION 20MG/ML	8087/21T	8087/21T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES 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
ONDANSETRON/KABI SOLUTION FOR INFUSION 0.08MG/ML	2751/23T	2751/23T	FRESENIUS KABI 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
ONDANSETRON/KABI SOLUTION FOR INFUSION 0.16MG/ML	2750/23T	2750/23T	FRESENIUS KABI 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
ONDANSETRON/KABI SOLUTION FOR INFUSION 0.08MG/ML	1577/23T, 1578/23T	1577/23T, 1578/23T	FRESENIUS KABI HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder 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
ONDANSETRON/KABI SOLUTION FOR INFUSION 0.16MG/ML	1575/23T, 1576/23T	1575/23T, 1576/23T	FRESENIUS KABI HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder 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
TEGLUTIK ORAL SUSPENSION 5MG/ML	9699/22T	9699/22T	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)*
TOPOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	1279/23T	1279/23T	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
TEGLUTIK ORAL SUSPENSION 5MG/ML	1153/23T	1153/23T	ITF HELLAS A.E.	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
ODELO TABLET, FILM COATED 2.5MG	701/23T, 702/23T	701/23T, 702/23T	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
ODELO TABLET, FILM COATED 20MG	695/23T, 696/23T	695/23T, 696/23T	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
ODELO TABLET, FILM COATED 10MG	699/23T, 700/23T	699/23T, 700/23T	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
ODELO TABLET, FILM COATED 15MG	697/23T, 698/23T	697/23T, 698/23T	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
FRAXIPARINE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 2850IU AXa/0.3ML	160/23T	160/23T	VIATRIS HEALTHCARE LIMITED.	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	159/23T	159/23T	VIATRIS HEALTHCARE LIMITED.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ZAOLIN CAPSULE, SOFT 20MG	2024/23T	2024/23T	PHARMAZAC 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)
ZAOLIN CAPSULE, SOFT 30MG	2023/23T	2023/23T	PHARMAZAC 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)
ZAOLIN CAPSULE, SOFT 80MG	2022/23T	2022/23T	PHARMAZAC 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)
VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	3131/22T	3131/22T	MERCK SHARP & DOHME BV	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
VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	9210/21T, 9211/21T	9210/21T, 9211/21T	MERCK SHARP & DOHME BV	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.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
DONEPEZIL KRKA TABLET, FILM COATED 5MG	2665/23T	2665/23T	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 - Change in the holding time of an intermediate
DONEPEZIL KRKA TABLET, FILM COATED 10MG	2664/23T	2664/23T	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 - Change in the holding time of an intermediate
CRESTOR TABLET, FILM COATED 40MG	2551/23T	2551/23T	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	2552/23T	2552/23T	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	2553/23T	2553/23T	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 5MG	2554/23T	2554/23T	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
VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	6794/22T, 6795/22T	6794/22T, 6795/22T	BAUSCH + LOMB IRELAND 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 - 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
DEXAMETHASONE/RAFARM [PF] EYE DROPS, SOLUTION 1MG/ML	3289/23T	3289/23T	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
NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	2309/23T	2309/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NICORETTE QUICKSPRAY OROMUCOSAL SPRAY, SOLUTION 1MG/DOSE	2308/23T	2308/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PLATEL TABLET, FILM COATED 75MG	1798/22T	1798/22T	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
EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	9546/22T	9546/22T	SANOFI PASTEUR.	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
CARMUSTINE ACCORD POWDER & SOLVENT FOR CONCENTRATE FOR SOL.FOR INF. 100MG	6588/22T	6588/22T	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 - Implementation of an agreed wording, no new data submitted
VINBLASTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	3318/23T, 3319/23T	3318/23T, 3319/23T	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 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
SOTAX TABLET 80MG	6098/22T, 6099/22T, 6100/22T, 6101/22T, 6102/22T	6098/22T, 6099/22T, 6100/22T, 6101/22T, 6102/22T	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
SORIL-MED LEMON LOZENGE 3MG	8579/22T	8579/22T	SAPIENS PHARMACEUTICALS LTD	A.z A.z - ADMINISTRATIVE CHANGES - 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
DINAPLEX CAPSULE, HARD 0.5MG/0.4MG	1649/23T	1649/23T	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
VIACORAM TABLET 3.5MG/2.5MG	5945/20T	5945/20T	LES LABORATOIRES SERVIER	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
VIACORAM TABLET 7MG/5MG	5944/20T	5944/20T	LES LABORATOIRES SERVIER	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
VIACORAM TABLET 3.5MG/2.5MG	5667/22T	5667/22T	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
VIACORAM TABLET 7MG/5MG	5668/22T	5668/22T	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
LOPERIUM TABLET 2MG	2432/23T, 2433/23T, 2434/23T, 2435/23T	2432/23T, 2433/23T, 2434/23T, 2435/23T	REMEDICA LTD	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.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 C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

MITOMYCIN ACCORD POWDER FOR SOLUTION FOR INJECTION/INFUSION 20MG/VIAL	7978/22T	7978/22T	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)*
MITOMYCIN ACCORD POWDER FOR SOLUTION FOR INJECTION/INFUSION 20MG/VIAL	4404/22T	4404/22T	ACCORD HEALTHCARE S.L.U	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
LIPOCOMB CAPSULE, HARD 10MG/10MG	2999/23T	2999/23T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	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
LIPOCOMB CAPSULE, HARD 20MG/10MG	2998/23T	2998/23T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	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
SUGAMMADEX ANABIOSIS SOLUTION FOR INJECTION 100MG/ML	1770/23T	1770/23T	ANABIOSIS PC.	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
ZOVIDUO CREAM (50MG/10MG)/G	368/23T, 369/23T, 370/23T, 371/23T, 372/23T, 373/23T	368/23T, 369/23T, 370/23T, 371/23T, 372/23T, 373/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	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)
CERTICAN TABLET 1MG	2608/23T	2608/23T	NOVARTIS IRELAND LIMITED	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
CERTICAN TABLET 0.25MG	2609/23T	2609/23T	NOVARTIS IRELAND LIMITED	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
CERTICAN TABLET 0.75MG	2606/23T	2606/23T	NOVARTIS IRELAND LIMITED	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
CERTICAN TABLET 0.5MG	2607/23T	2607/23T	NOVARTIS IRELAND LIMITED	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
ARIPIPRAZOLE AUROBINDO TABLET 10MG	6241/22T, 6242/22T, 6243/22T, 6244/22T	6241/22T, 6242/22T, 6243/22T, 6244/22T	AUROBINDO PHARMA (MALTA) 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.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
ARIPIPRAZOLE AUROBINDO TABLET 30MG	6233/22T, 6234/22T, 6235/22T, 6236/22T	6233/22T, 6234/22T, 6235/22T, 6236/22T	AUROBINDO PHARMA (MALTA) 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.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
ARIPIPRAZOLE AUROBINDO TABLET 15MG	6237/22T, 6238/22T, 6239/22T, 6240/22T	6237/22T, 6238/22T, 6239/22T, 6240/22T	AUROBINDO PHARMA (MALTA) 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.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
VALGANCICLOVIR ACCORD TABLET, FILM COATED 450MG	1637/23T, 1638/23T, 1639/23T, 1640/23T	1637/23T, 1638/23T, 1639/23T, 1640/23T	ACCORD HEALTHCARE S.L.U	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.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
ARIPIPRAZOLE KRKA TABLET 10MG	2050/23T	2050/23T	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
ARIPIPRAZOLE KRKA TABLET 30MG	2048/23T	2048/23T	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
ARIPIPRAZOLE KRKA TABLET 15MG	2049/23T	2049/23T	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
ARIPIPRAZOLE KRKA TABLET 5MG	2051/23T	2051/23T	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
CLARISCAN SOLUTION FOR INJECTION 0.5MMOL/ML	2077/23T, 2078/23T	2077/23T, 2078/23T	GE HEALTHCARE AS	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 RMP changes (e.g. agreed wording + template change)
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	2617/23T	2617/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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
DEXETA EYE DROPS, SOLUTION 1.5MG/ML	3036/23T	3036/23T	NEWLINE PHARMA, S.L.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
GROWFIN TABLET, FILM COATED 1MG	3800/23T	3800/23T	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)*
FRISIUM TABLET 10MG	2466/23T	2466/23T	SANOFI-AVENTIS GROUPE	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AUGMENTIN TABLET, FILM COATED 1G	2712/23T	2712/23T	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

AUGMENTIN TABLET, FILM COATED 500MG/125MG	2713/23T	2713/23T	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
GEMCITABINE ACCORD POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	3353/23T	3353/23T	ACCORD HEALTHCARE S.L.U	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
GEMCITABINE ACCORD POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	3352/23T	3352/23T	ACCORD HEALTHCARE S.L.U	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
BETAISODONA GARGLE/MOUTHWASH 1% W/V	3325/23T	3325/23T	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

LOSARTAN POTASSIUM JUBILANT TABLET, FILM COATED 50MG	3286/23T	3286/23T	JUBILANT PHARMACEUTICALS NV	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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/MYLAN TABLET 10MG/20MG	2130/23T, 2131/23T	2130/23T, 2131/23T	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
EZETIMIBE+SIMVASTATIN/MYLAN TABLET 10MG/40MG	2128/23T, 2129/23T	2128/23T, 2129/23T	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
EZETIMIBE+SIMVASTATIN/MYLAN TABLET 10MG/20MG	3011/23T	3011/23T	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)
EZETIMIBE+SIMVASTATIN/MYLAN TABLET 10MG/40MG	3010/23T	3010/23T	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)
LIPITOR TABLET, FILM COATED 20MG	5195/22T, 5196/22T, 5197/22T	5195/22T, 5196/22T, 5197/22T	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LIPITOR TABLET, FILM COATED 40MG	5198/22T, 5199/22T, 5200/22T	5198/22T, 5199/22T, 5200/22T	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LIPITOR TABLET, FILM COATED 10MG	5192/22T, 5193/22T, 5194/22T	5192/22T, 5193/22T, 5194/22T	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LIPITOR TABLET, CHEWABLE 5MG	5201/22T, 5202/22T, 5203/22T	5201/22T, 5202/22T, 5203/22T	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LIPITOR TABLET, CHEWABLE 40MG	5210/22T, 5211/22T, 5212/22T	5210/22T, 5211/22T, 5212/22T	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally

				Authorised Products
LIPITOR TABLET, CHEWABLE 10MG	5204/22T, 5205/22T, 5206/22T	5204/22T, 5205/22T, 5206/22T	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LIPITOR TABLET, CHEWABLE 20MG	5207/22T, 5208/22T, 5209/22T	5207/22T, 5208/22T, 5209/22T	UPJOHN HELLAS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
CASPOFUNGIN DEMO POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 50MG/VIAL	3766/23T	3766/23T	DEMO 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
CASPOFUNGIN DEMO POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 70MG/VIAL	3765/23T	3765/23T	DEMO 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
NUTRIFLEX OMEGA PERI EMULSION FOR INFUSION	1812/23T, 1813/23T, 1814/23T, 1815/23T, 1816/23T, 1817/23T, 1818/23T, 1819/23T	1812/23T, 1813/23T, 1814/23T, 1815/23T, 1816/23T, 1817/23T, 1818/23T, 1819/23T	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 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)
BLISSEL VAGINAL GEL 50MCG/G	2055/23T	2055/23T	ITF HELLAS A.E.	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

NUTRIFLEX OMEGA PERI EMULSION FOR INFUSION	9845/22T, 9846/22T, 9847/22T, 9848/22T, 9849/22T, 9850/22T	9845/22T, 9846/22T, 9847/22T, 9848/22T, 9849/22T, 9850/22T	B. BRAUN MELSUNGEN 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.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.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
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	2871/23T	2871/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	2874/23T	2874/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	2872/23T	2872/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	2873/23T	2873/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EMTRICITABINE/TENOFOVIR DISOPROXIL SANDOZ TABLET, FILM COATED 200MG/245MG	2673/23T	2673/23T	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
ROCURONIUM B.BRAUN SOLUTION FOR INJECTION OR INFUSION 10MG/ML	3265/23T, 3266/23T	3265/23T, 3266/23T	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
CODANOL TABLET	1590/23T	1590/23T	CRESCENT PHARMA INTERNATIONAL LIMITED	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
PEMETREXED SANDOZ CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	772/23T	772/23T	SANDOZ PHARMACEUTICALS D.D.	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
PEMETREXED SANDOZ CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	482/23T	482/23T	SANDOZ PHARMACEUTICALS D.D.	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
MEPIDENTAL SOLUTION FOR INJECTION IN A CARTRIDGE 30MG/ML	7927/22T	7927/22T	INIBSA DENTAL S.L.U.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	2406/23T	2406/23T	VIATRIS HEALTHCARE LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	2405/23T	2405/23T	VIATRIS HEALTHCARE LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES -

				Change in the name and/or address of the marketing authorisation holder
DUODART CAPSULE, HARD	2159/23T, 2160/23T	2159/23T, 2160/23T	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
EPIDUO GEL (0.001G/0.025G)G	1734/23T	1734/23T	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	1732/23T	1732/23T	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	1730/23T	1730/23T	GALDERMA INTERNATIONAL ,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LOCERYL MEDICATED NAIL LACQUER 5% (W/V)	1731/23T	1731/23T	GALDERMA INTERNATIONAL ,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EPIDUO FORTE GEL 0.3%/2.5%	1733/23T	1733/23T	GALDERMA INTERNATIONAL ,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	3262/23T, 3263/23T, 3264/23T	3262/23T, 3263/23T, 3264/23T	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 - 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NIZORAL CREAM 2%	2528/23T	2528/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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
FLUCOZAL CAPSULE, HARD 200MG	3281/23T	3281/23T	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
FLUCOZAL CAPSULE, HARD 50MG	3283/23T	3283/23T	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
FLUCOZAL CAPSULE, HARD 100MG	3282/23T	3282/23T	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
PORPHYROCIN TABLET, FILM COATED 250MG	1644/23T	1644/23T	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
EZETIMIBE/MYLAN TABLET 10MG	2101/23T, 2102/23T	2101/23T, 2102/23T	MYLAN PHARMACEUTICALS 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
CLINIMIX N14G30E SOLUTION FOR INFUSION	4884/22T, 4885/22T, 4886/22T, 4887/22T	4884/22T, 4885/22T, 4886/22T, 4887/22T	BAXTER (HELLAS) EPE	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)
STREPFEN DIRECT HONEY & LEMON OROMUCOSAL SPRAY, SOLUTION 8.75MG	5014/21T	5014/21T	RECKITT BENCKISER HELLAS HEALTHCARE SA	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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	2379/23T	2379/23T	SANOFI WINTHROP INDUSTRIE.	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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	2381/23T	2381/23T	SANOFI WINTHROP INDUSTRIE.	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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	2380/23T	2380/23T	SANOFI WINTHROP INDUSTRIE.	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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	2378/23T	2378/23T	SANOFI WINTHROP INDUSTRIE.	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
ZYVOXID SOLUTION FOR INFUSION 2MG/ML	2315/23T	2315/23T	PFIZER HELLAS AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZYVOXID TABLET, FILM COATED 600MG	2314/23T	2314/23T	PFIZER HELLAS AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

MERONEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	2317/23T	2317/23T	PFIZER HELLAS AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FUNGUSTATIN CAPSULE, HARD 150MG	2316/23T	2316/23T	PFIZER HELLAS AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TICOVAC JUNIOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.25ML/DOSE	2313/23T	2313/23T	PFIZER HELLAS AE	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	2312/23T	2312/23T	PFIZER HELLAS AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VESICARE TABLET, FILM COATED 10MG	2446/23T, 2447/23T, 2448/23T	2446/23T, 2447/23T, 2448/23T	ASTELLAS PHARMACEUTICALS A.E.B.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 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.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
VESICARE TABLET, FILM COATED 5MG	2449/23T, 2450/23T, 2451/23T	2449/23T, 2450/23T, 2451/23T	ASTELLAS PHARMACEUTICALS A.E.B.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 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.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
CANDESARTAN TAD TABLET 16MG	3239/23T	3239/23T	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
CANDESARTAN TAD TABLET 32MG	3238/23T	3238/23T	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
SYNTOCLAV BIS POWDER FOR ORAL SUSPENSION 457MG/5ML	2269/23T	2269/23T	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
CARBOPLATIN/HOSPIRA SOLUTION FOR INFUSION 10MG/ML	1059/23T	1059/23T	PFIZER HELLAS AE	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
CARBOPLATIN/HOSPIRA SOLUTION FOR INFUSION 10MG/ML	904/23T	904/23T	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
EZETIMIBE+SIMVASTATIN/MYLAN TABLET 10MG/20MG	6868/22T	6868/22T	MYLAN IRELAND 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
EZETIMIBE+SIMVASTATIN/MYLAN TABLET 10MG/10MG	6869/22T	6869/22T	MYLAN IRELAND 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
EZETIMIBE+SIMVASTATIN/MYLAN TABLET 10MG/40MG	6867/22T	6867/22T	MYLAN IRELAND 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/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
EZETIMIBE/MYLAN TABLET 10MG	6866/22T	6866/22T	MYLAN PHARMACEUTICALS 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
TOPOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	389/23T	389/23T	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)*
BUDENOFALK UNO GASTRO-RESISTANT GRANULES 9MG	1542/23T, 1543/23T, 1544/23T	1542/23T, 1543/23T, 1544/23T	DR. FALK 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) 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)*
GADOGRAF SOLUTION FOR INJECTION 1.0MMOL/ML	5585/22T	5585/22T	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	5584/22T	5584/22T	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)	5587/22T	5587/22T	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)	5586/22T	5586/22T	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 SOLUTION FOR INJECTION 1MMOL/ML	5583/22T	5583/22T	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)
PRIMOVIST SOLUTION FOR INJECTION IN PREFILLED SYRINGES 0.25MMOL/ML	5582/22T	5582/22T	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)
BROTMIN TABLET, FILM COATED 850MG	1493/23T	1493/23T	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)
BROTMIN TABLET, FILM COATED 1000MG	1492/23T	1492/23T	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)
BROTMIN TABLET, FILM COATED 500MG	1494/23T	1494/23T	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)
EXATRON TABLET, FILM COATED	1963/23T	1963/23T	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 POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/200MG	2146/23T	2146/23T	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
HYDRALAZINE TABLET, COATED 25MG	875/23T, 876/23T	875/23T, 876/23T	REMEDICA 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.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
HYDRALAZINE TABLET, COATED 50MG	873/23T, 874/23T	873/23T, 874/23T	REMEDICA 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.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
ADVANTAN CUTANEOUS SOLUTION 0.1% (W/V)	3302/23T	3302/23T	LEO PHARMA A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SYNTOCLAV TABLET, FILM COATED 875/125MG	2151/23T	2151/23T	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
ZOLARAM TABLET 0.25MG	1508/23T	1508/23T	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
ZOLARAM TABLET 0.5MG	1507/23T	1507/23T	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
ZOLARAM TABLET 1MG	1506/23T	1506/23T	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
PULMOTON INHALATION POWDER, PRE-DISPENSED (200+6) MCG/DOSE	577/23T, 578/23T, 583/23T, 584/23T	577/23T, 578/23T, 583/23T, 584/23T	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.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
PULMOTON INHALATION POWDER, PRE-DISPENSED (100+6) MCG/DOSE	579/23T, 580/23T, 585/23T, 586/23T	579/23T, 580/23T, 585/23T, 586/23T	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.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
PULMOTON INHALATION POWDER, PRE-DISPENSED (400+12) MCG/DOSE	575/23T, 576/23T, 581/23T, 582/23T	575/23T, 576/23T, 581/23T, 582/23T	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.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
TIORESP INHALATION POWDER, PRE-DISPENSED 10MCG/DOSE	3235/23T	3235/23T	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
DEXMEDETOMIDINE/BAXTER CONCENTRATE FOR SOLUTION FOR INFUSION 100MCG/ML	2662/23T	2662/23T	BAXTER HOLDING 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)
PORPHYROCIN FORTE POWDER FOR ORAL SUSPENSION 250MG/5ML	1648/23T	1648/23T	MEDOCHEMIE 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
HEMOSOL B0 SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS	1459/23T	1459/23T	BAXTER HOLDING 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)
SYMBICORT TURBUHALER POWDER FOR INHALATION 320MCG/9MCG	1751/23T	1751/23T	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	1746/23T	1746/23T	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	1747/23T	1747/23T	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	1748/23T	1748/23T	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	1745/23T	1745/23T	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	1749/23T	1749/23T	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	1739/23T	1739/23T	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	1741/23T	1741/23T	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	1742/23T	1742/23T	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	1740/23T	1740/23T	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	1750/23T	1750/23T	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	1743/23T	1743/23T	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	1738/23T	1738/23T	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	1744/23T	1744/23T	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PICOPREP POWDER FOR ORAL SOLUTION	8522/21T	8522/21T	FERRING HELLAS MEPE	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
BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	565/23T	565/23T	ABBVIE PHARMACEUTICALS 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
BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	565/23T	565/23T	ABBVIE PHARMACEUTICALS 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
BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	564/23T	564/23T	ABBVIE PHARMACEUTICALS 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
BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	564/23T	564/23T	ABBVIE PHARMACEUTICALS 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
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	563/23T	563/23T	ABBVIE PHARMACEUTICALS 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
BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	566/23T	566/23T	ABBVIE PHARMACEUTICALS 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
BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	566/23T	566/23T	ABBVIE PHARMACEUTICALS 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
TOURAM TABLET, FILM COATED 5MG	1500/23T	1500/23T	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 10MG	1499/23T	1499/23T	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
MEZAVANT GASTRO-RESISTANT, PROLONGED RELEASE TABLETS 1200MG	667/23T	667/23T	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ASPRO CLEAR EFFERVESCENT TABLET 300MG	3017/23T	3017/23T	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
ASACOL ENEMA 4G/100ML	1101/23T, 1102/23T, 1103/23T	1101/23T, 1102/23T, 1103/23T	TILLOTTS PHARMA GMBH	B.IV.z B.IV.z - QUALITY CHANGES - Medical Devices - Other variation 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.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
ASACOL TABLET, GASTRO-RESISTANT 400MG	949/23T	949/23T	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
ASACOL TABLET, GASTRO-RESISTANT 400MG	2538/23T, 2539/23T, 2540/23T	2538/23T, 2539/23T, 2540/23T	TILLOTTS 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) - Deletion of a supplier
URACTONUM TABLET 25MG	726/23T, 727/23T	726/23T, 727/23T	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
URACTONUM TABLET 100MG	724/23T, 725/23T	724/23T, 725/23T	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
METHOTREXATE TABLET, FILM COATED 2.5MG	1771/23T	1771/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
COSTI TABLET 10MG	674/23T, 675/23T, 676/23T, 677/23T, 678/23T, 679/23T, 680/23T, 681/23T, 682/23T, 683/23T	674/23T, 675/23T, 676/23T, 677/23T, 678/23T, 679/23T, 680/23T, 681/23T, 682/23T, 683/23T	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
TIENAM POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	636/23T	636/23T	MERCK SHARP & DOHME BV	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
STATEZOL TABLET, FILM COATED 20MG/10MG	3158/23T	3158/23T	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
STATEZOL TABLET, FILM COATED 5MG/10MG	3160/23T	3160/23T	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
STATEZOL TABLET, FILM COATED 10MG/10MG	3159/23T	3159/23T	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
STATEZOL TABLET, FILM COATED 40MG/10MG	3157/23T	3157/23T	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

STATEZOL TABLET, FILM COATED 10MG/10MG	2784/23T, 2785/23T	2784/23T, 2785/23T	DELORBIS PHARMACEUTICALS 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) 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
STATEZOL TABLET, FILM COATED 20MG/10MG	2782/23T, 2783/23T	2782/23T, 2783/23T	DELORBIS PHARMACEUTICALS 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) 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
STATEZOL TABLET, FILM COATED 5MG/10MG	2786/23T, 2787/23T	2786/23T, 2787/23T	DELORBIS PHARMACEUTICALS 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) 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
STATEZOL TABLET, FILM COATED 40MG/10MG	2780/23T, 2781/23T	2780/23T, 2781/23T	DELORBIS PHARMACEUTICALS 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) 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
STATEZOL TABLET, FILM COATED 40MG/10MG	2610/23T	2610/23T	DELORBIS PHARMACEUTICALS 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
STATEZOL TABLET, FILM COATED 5MG/10MG	2612/23T	2612/23T	DELORBIS PHARMACEUTICALS 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
STATEZOL TABLET, FILM COATED 10MG/10MG	2611/23T	2611/23T	DELORBIS PHARMACEUTICALS 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
STATEZOL TABLET, FILM COATED 20MG/10MG	2613/23T	2613/23T	DELORBIS PHARMACEUTICALS 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
GENEMENT TABLET, FILM COATED 20MG	3096/23T	3096/23T	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 do not include batch release
GENEMENT TABLET, FILM COATED 5MG	3097/23T	3097/23T	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 do not include batch release
AIRTAL TABLET, FILM COATED 100MG	8644/22T	8644/22T	ALMIRALL S.A.	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
STATEZOL TABLET, FILM COATED 40MG/10MG	2486/23T	2486/23T	DELORBIS PHARMACEUTICALS LTD	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)
STATEZOL TABLET, FILM COATED 10MG/10MG	2488/23T	2488/23T	DELORBIS PHARMACEUTICALS LTD	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)
STATEZOL TABLET, FILM COATED 5MG/10MG	2489/23T	2489/23T	DELORBIS PHARMACEUTICALS LTD	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)
STATEZOL TABLET, FILM COATED 20MG/10MG	2487/23T	2487/23T	DELORBIS PHARMACEUTICALS LTD	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)
OPTIVATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	9485/21T	9485/21T	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
ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 40MG	8379/21T, 8380/21T	8379/21T, 8380/21T	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	8377/21T, 8378/21T	8377/21T, 8378/21T	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
ENTONOX MEDICINAL GAS, COMPRESSED	171/23T, 172/23T	171/23T, 172/23T	AGA AB	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or

				deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	365/23T	365/23T	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)
SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	364/23T	364/23T	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)
TRAVOPROST/RAFARM EYE DROPS, SOLUTION 40MCG/ML	7765/22T	7765/22T	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
METRONIDAZOLE VIOSER SOLUTION FOR INFUSION 500MG/100ML	966/23T	966/23T	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	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.
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	2057/23T, 2058/23T	2057/23T, 2058/23T	ASTELLAS PHARMACEUTICALS A.E.B.E.	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.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
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/VIAL	1598/23T	1598/23T	SEACROSS PHARMA (EUROPE) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 500MG/VIAL	1597/23T	1597/23T	SEACROSS PHARMA (EUROPE) LIMITED	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
RUPAFIN TABLET 10MG	1929/23T	1929/23T	J. URIACH Y COMPANIA 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
RUPAFIN ORAL SOLUTION 1MG/ML	1930/23T	1930/23T	J. URIACH Y COMPANIA 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
ARESTON TABLET, FILM COATED 12.5MG	1607/23T	1607/23T	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
OLMESARTAN TAD TABLET, FILM COATED 40MG	1692/22T, 1693/22T	1692/22T, 1693/22T	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/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
OLMESARTAN TAD TABLET, FILM COATED 20MG	1690/22T, 1691/22T	1690/22T, 1691/22T	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
OLMESARTAN TAD TABLET, FILM COATED 10MG	1688/22T, 1689/22T	1688/22T, 1689/22T	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 AUROBINDO TABLET, GASTRO-RESISTANT 20MG	670/23T	670/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 40MG	669/23T	669/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
TRIATEC PLUS TABLET 5MG/25MG	1928/23T	1928/23T	SANOFI WINTHROP INDUSTRIE.	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
ASPENDOS TABLET 100MG	2059/23T	2059/23T	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

DYMISTA NASAL SPRAY, SUSPENSION	2183/23T	2183/23T	MEDA PHARMACEUTICALS 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
LACTULOSE RESOLUTION ORAL SOLUTION 3.3G/5ML	693/23T, 694/23T	693/23T, 694/23T	RELAX LTD	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 - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

HEXARHINAL PLUS NASAL SPRAY, SOLUTION (1MG/50MG)/ML	567/23T, 568/23T	567/23T, 568/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.IV.z B.IV.z - QUALITY CHANGES - Medical Devices - 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
FENODEX TABLET, FILM COATED 12.5MG	8092/22T	8092/22T	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
FENODEX TABLET, FILM COATED 25MG	8091/22T	8091/22T	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
LETYBO POWDER FOR SOLUTION FOR INJECTION 50U	8710/22T	8710/22T	CROMA-PHARMA GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	1004/23T, 1005/23T	1004/23T, 1005/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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.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
SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5MCG	1865/23T	1865/23T	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SMOFKABIVEN ELECTROLYTE FREE EMULSION FOR INFUSION	6918/22T, 6919/22T	6918/22T, 6919/22T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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.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)
SMOFKABIVEN EMULSION FOR INFUSION	6920/22T, 6921/22T	6920/22T, 6921/22T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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.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)
RAPIBLOC CONCENTRATE FOR SOLUTION FOR INJECTION 20MG/2ML	8906/22T	8906/22T	AMOMED PHARMA GMBH.	B.I.a.1.g B.I.a.1.g - 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 new manufacturer of the active substance that is not supported by an ASMF and requires significant update to the relevant active substance section of the dossier

RAPIBLOC POWDER FOR SOLUTION FOR INFUSION 300MG/VIAL	8905/22T	8905/22T	AMOMED PHARMA GMBH.	B.I.a.1.g B.I.a.1.g - 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 new manufacturer of the active substance that is not supported by an ASMF and requires significant update to the relevant active substance section of the dossier
OLANZAPINE AUROBINDO TABLET 5MG	990/23T	990/23T	AUROBINDO PHARMA (MALTA) LIMITED	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
OLANZAPINE AUROBINDO TABLET 10MG	989/23T	989/23T	AUROBINDO PHARMA (MALTA) LIMITED	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
LIPOCOMB CAPSULE, HARD 20MG/10MG	1888/23T, 1889/23T, 1890/23T, 1891/23T, 1892/23T, 1893/23T, 1894/23T, 1895/23T	1888/23T, 1889/23T, 1890/23T, 1891/23T, 1892/23T, 1893/23T, 1894/23T, 1895/23T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	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.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.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

LIPOCOMB CAPSULE, HARD 10MG/10MG	1896/23T, 1897/23T, 1898/23T, 1899/23T, 1900/23T, 1901/23T, 1902/23T, 1903/23T	1896/23T, 1897/23T, 1898/23T, 1899/23T, 1900/23T, 1901/23T, 1902/23T, 1903/23T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	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.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.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
RAMI-AMLO CAPSULE, HARD (5+5)MG	2335/23T	2335/23T	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
RAMI-AMLO CAPSULE, HARD (2.5+5)MG	2336/23T	2336/23T	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
RAMI-AMLO CAPSULE, HARD (5+10)MG	2334/23T	2334/23T	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
RAMI-AMLO CAPSULE, HARD (10+5)MG	2333/23T	2333/23T	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
RAMI-AMLO CAPSULE, HARD (10+10)MG	2332/23T	2332/23T	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
DALMEVIN TABLET 50MG	992/23T	992/23T	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
LINEZOLID ACCORD SOLUTION FOR INFUSION 2MG/ML	5123/22T	5123/22T	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
VALGANCICLOVIR PHARMATHEN TABLET, FILM COATED 450MG	1413/23T	1413/23T	PHARMATHEN 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
BIORPHEN SOLUTION FOR INJECTION 10MG/ML	1600/23T, 1601/23T	1600/23T, 1601/23T	SINTETICA 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
BIORPHEN SOLUTION FOR INJECTION OR INFUSION 0.1MG/ML	1602/23T, 1603/23T	1602/23T, 1603/23T	SINTETICA 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
EPHEDRINE SINTETICA SOLUTION FOR INJECTION 50MG/ML	1829/23T, 1830/23T	1829/23T, 1830/23T	SINTETICA 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
EPHEDRINE SINTETICA SOLUTION FOR INJECTION 10MG/ML	1831/23T, 1832/23T	1831/23T, 1832/23T	SINTETICA 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
ROVASYN TABLET, FILM COATED 5MG	2255/23T, 2256/23T, 2257/23T, 2258/23T, 2259/23T, 2260/23T, 2261/23T, 2262/23T, 2263/23T	2255/23T, 2256/23T, 2257/23T, 2258/23T, 2259/23T, 2260/23T, 2261/23T, 2262/23T, 2263/23T	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
ROVASYN TABLET, FILM COATED 40MG	2228/23T, 2229/23T, 2230/23T, 2231/23T, 2232/23T, 2233/23T, 2234/23T,	2228/23T, 2229/23T, 2230/23T, 2231/23T, 2232/23T, 2233/23T, 2234/23T,	CODAL-SYNTO LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated

	2235/23T, 2236/23T	2235/23T, 2236/23T		Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROVASYN TABLET, FILM COATED 20MG	2237/23T, 2238/23T, 2239/23T, 2240/23T, 2241/23T, 2242/23T, 2243/23T, 2244/23T, 2245/23T	2237/23T, 2238/23T, 2239/23T, 2240/23T, 2241/23T, 2242/23T, 2243/23T, 2244/23T, 2245/23T	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
ROVASYN TABLET, FILM COATED 10MG	2246/23T, 2247/23T, 2248/23T, 2249/23T, 2250/23T, 2251/23T, 2252/23T, 2253/23T, 2254/23T	2246/23T, 2247/23T, 2248/23T, 2249/23T, 2250/23T, 2251/23T, 2252/23T, 2253/23T, 2254/23T	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
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 20MG	1833/23T, 1834/23T	1833/23T, 1834/23T	TAD 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
SEDISTRESS TABLET, COATED 200MG	226/23T, 953/23T	226/23T, 953/23T	TILMAN 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 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
SEDISTRESS TABLET, COATED 200MG	226/23T, 953/23T	226/23T, 953/23T	TILMAN 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 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
GRAFALON CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	233/23T	233/23T	NEOVII BIOTECH 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
CONCERTA TABLET, PROLONGED-RELEASE 36MG	1374/23T	1374/23T	JANSSEN-CILAG INTERNATIONAL NV	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
CONCERTA TABLET, PROLONGED-RELEASE 18MG	1375/23T	1375/23T	JANSSEN-CILAG INTERNATIONAL NV	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
CONCERTA TABLET, PROLONGED-RELEASE 54MG	1373/23T	1373/23T	JANSSEN-CILAG INTERNATIONAL NV	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
ENSTILAR CUTANEOUS FOAM (50MCG/0.5MG)/G	3/23T	3/23T	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

ATACAND PLUS TABLET 32MG/25MG	8954/22T, 8955/22T, 8956/22T, 8957/22T, 8958/22T, 8959/22T, 8960/22T	8954/22T, 8955/22T, 8956/22T, 8957/22T, 8958/22T, 8959/22T, 8960/22T	CHEPLAPHARM ARZNEIMITTEL GMBH.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or 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 f B.II.a.3.b.1 B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (ex B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied durin B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied durin 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.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED

				PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo
ATACAND PLUS TABLET 16MG/12.5MG	8968/22T, 8969/22T, 8970/22T, 8971/22T, 8972/22T, 8973/22T	8968/22T, 8969/22T, 8970/22T, 8971/22T, 8972/22T, 8973/22T	CHEPLAPHARM ARZNEIMITTEL GMBH.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or 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 f B.II.a.3.b.1 B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (ex B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied durin B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied durin 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.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo
ATACAND PLUS TABLET 32MG/12.5MG	8961/22T, 8962/22T, 8963/22T, 8964/22T, 8965/22T, 8966/22T, 8967/22T	8961/22T, 8962/22T, 8963/22T, 8964/22T, 8965/22T, 8966/22T, 8967/22T	CHEPLAPHARM ARZNEIMITTEL GMBH.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or 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 f B.II.a.3.b.1 B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (ex B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied durin B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied durin 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.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo
OLIMEL PERI N4E EMULSION FOR INFUSION	1043/23T, 1044/23T	1043/23T, 1044/23T	BAXTER (HELLAS) EPE	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)
OLIMEL N9E EMULSION FOR INFUSION	1039/23T, 1040/23T	1039/23T, 1040/23T	BAXTER (HELLAS) EPE	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)
OLIMEL N12E EMULSION FOR INFUSION	1037/23T, 1038/23T	1037/23T, 1038/23T	BAXTER (HELLAS) EPE	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)
OLIMEL N7 EMULSION FOR INFUSION	1035/23T, 1036/23T	1035/23T, 1036/23T	BAXTER (HELLAS) EPE	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)
OLIMEL N9 EMULSION FOR INFUSION	1033/23T, 1034/23T	1033/23T, 1034/23T	BAXTER (HELLAS) EPE	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)
OLIMEL N7E EMULSION FOR INFUSION	1041/23T, 1042/23T	1041/23T, 1042/23T	BAXTER (HELLAS) EPE	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)
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	8179/22T	8179/22T	GRIFOLS DEUTSCHLAND GMBH.	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

CIPROXIN TABLET, FILM COATED 500MG	1286/23T, 1287/23T	1286/23T, 1287/23T	BAYER HELLAS ABEE	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
CRESTOR TABLET, FILM COATED 40MG	7014/22T	7014/22T	ASTRAZENECA AB	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.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
CRESTOR TABLET, FILM COATED 20MG	7015/22T	7015/22T	ASTRAZENECA AB	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.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
CRESTOR TABLET, FILM COATED 5MG	7017/22T	7017/22T	ASTRAZENECA AB	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.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
CRESTOR TABLET, FILM COATED 10MG	7016/22T	7016/22T	ASTRAZENECA AB	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.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

VALGANCICLOVIR ACCORD TABLET, FILM COATED 450MG	418/23T	418/23T	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)*
VERSATIS MEDICATED PLASTER 700MG	101/23T, 102/23T, 103/23T	101/23T, 102/23T, 103/23T	GRUNENTHAL GMBH	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.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
BUTOLIR NEBULISER SUSPENSION 1MG/2ML	78/23T	78/23T	NORIDEM ENTERPRISES 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 -
BUTOLIR NEBULISER SUSPENSION 0.5MG/2ML	79/23T	79/23T	NORIDEM ENTERPRISES 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 -
DAPTOMYCIN NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	1321/23T	1321/23T	NORIDEM ENTERPRISES 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)
DAPTOMYCIN NORIDEM POWDER FOR SOLUTION FOR INJECTION/INFUSION 350MG/VIAL	1322/23T	1322/23T	NORIDEM ENTERPRISES 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)
ATORVASTATIN AUROBINDO TABLET, FILM COATED 20MG	1925/23T	1925/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
ATORVASTATIN AUROBINDO TABLET, FILM COATED 40MG	1924/23T	1924/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient

ATORVASTATIN AUROBINDO TABLET, FILM COATED 10MG	1926/23T	1926/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
RUPAFIN TABLET 10MG	382/23T, 383/23T	382/23T, 383/23T	J. URIACH Y COMPANIA 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.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 -
AUGMENTIN ES POWDER FOR ORAL SUSPENSION (600+42.9)MG/5ML	132/23T	132/23T	GLAXOSMITHKLINE (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)
LIPOCAT TABLET, FILM COATED 10MG/10MG	1671/23T	1671/23T	ELPEN PHARMACEUTICAL CO INC	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
LIPOCAT TABLET, FILM COATED 10MG/20MG	1670/23T	1670/23T	ELPEN PHARMACEUTICAL CO INC	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
LIPOCAT TABLET, FILM COATED 10MG/40MG	1669/23T	1669/23T	ELPEN PHARMACEUTICAL CO INC	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
LIPOCAT TABLET, FILM COATED 10MG/80MG	1668/23T	1668/23T	ELPEN PHARMACEUTICAL CO INC	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
ZYRTEC TABLET, FILM COATED 10MG	354/23T	354/23T	UCB PHARMA 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)
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	9741/22T, 9742/22T, 9743/22T, 9744/22T	9741/22T, 9742/22T, 9743/22T, 9744/22T	ABBVIE PHARMACEUTICALS S.A.	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	9753/22T, 9754/22T, 9755/22T, 9756/22T	9753/22T, 9754/22T, 9755/22T, 9756/22T	ABBVIE PHARMACEUTICALS S.A.	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	9749/22T, 9750/22T, 9751/22T, 9752/22T	9749/22T, 9750/22T, 9751/22T, 9752/22T	ABBVIE PHARMACEUTICALS S.A.	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 200 UNITS	9745/22T, 9746/22T, 9747/22T, 9748/22T	9745/22T, 9746/22T, 9747/22T, 9748/22T	ABBVIE PHARMACEUTICALS S.A.	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
TICABRIL TABLET, FILM COATED 60MG	1840/23T	1840/23T	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
TICABRIL TABLET, FILM COATED 90MG	1839/23T	1839/23T	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
AMARYL TABLET 4MG	848/23T	848/23T	SANOFI WINTHROP INDUSTRIE.	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
AMARYL TABLET 1MG	851/23T	851/23T	SANOFI WINTHROP INDUSTRIE.	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
AMARYL TABLET 2MG	850/23T	850/23T	SANOFI WINTHROP INDUSTRIE.	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
AMARYL TABLET 3MG	849/23T	849/23T	SANOFI WINTHROP INDUSTRIE.	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
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 37.5MG	9628/22T	9628/22T	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
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	9627/22T	9627/22T	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
ELIFY XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	9626/22T	9626/22T	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
LEVOTHYROXINE ACCORD TABLET 50MCG	457/22T	457/22T	ACCORD HEALTHCARE S.L.U	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
LEVOTHYROXINE ACCORD TABLET 100MCG	458/22T	458/22T	ACCORD HEALTHCARE S.L.U	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
LEVOTHYROXINE ACCORD TABLET 25MCG	456/22T	456/22T	ACCORD HEALTHCARE S.L.U	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
INFLUVAC SUB-UNIT TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	9323/22T, 9324/22T, 9325/22T	9323/22T, 9324/22T, 9325/22T	VIATRIS HEALTHCARE LIMITED.	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.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.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
PROLUTEX SOLUTION FOR INJECTION 25MG	797/23T	797/23T	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
TECHNESCAN SESTAMIBI POWDER FOR SOLUTION FOR INJECTION 1MG/VIAL	781/23T	781/23T	CURIUM NETHERLANDS B.V.	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
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	663/23T	663/23T	BAXALTA INNOVATIONS GMBH	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
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	661/23T	661/23T	BAXALTA INNOVATIONS GMBH	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
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	662/23T	662/23T	BAXALTA INNOVATIONS GMBH	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
MECOLZINE TABLET, GASTRO-RESISTANT 500MG	911/23T	911/23T	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 TABLET, GASTRO-RESISTANT 1000MG	910/23T	910/23T	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
BLOXAZOC TABLET, PROLONGED-RELEASE 200MG	1026/23T	1026/23T	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
BLOXAZOC TABLET, PROLONGED-RELEASE 100MG	1023/23T	1023/23T	TAD PHARMA GMBH	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
BLOXAZOC TABLET, PROLONGED-RELEASE 25MG	1025/23T	1025/23T	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
BLOXAZOC TABLET, PROLONGED-RELEASE 50MG	1024/23T	1024/23T	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
ULTRAVIST 370 SOLUTION FOR INJECTION 76.9%	8673/22T	8673/22T	BAYER HELLAS ABEE	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
ULTRAVIST 300 SOLUTION FOR INJECTION 62.34%	8674/22T	8674/22T	BAYER HELLAS ABEE	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
DOVOBET OINTMENT	7/23T	7/23T	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
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	6848/21T	6848/21T	MUNDIPHARMA PHARMACEUTICALS LTD	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
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	6845/21T	6845/21T	MUNDIPHARMA PHARMACEUTICALS LTD	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
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	6847/21T	6847/21T	MUNDIPHARMA PHARMACEUTICALS LTD	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
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	6846/21T	6846/21T	MUNDIPHARMA PHARMACEUTICALS LTD	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
CARBON DIOXIDE LINDE LIQUEFIED MEDICINAL GAS MEDICINAL GAS, LIQUEFIED 100%	163/23T	163/23T	LINDE GAZ MAGYARORSZAG ZRT	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)
ATORVASTATIN AUROBINDO TABLET, FILM COATED 10MG	485/23T	485/23T	AUROBINDO PHARMA (MALTA) 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)*
ATORVASTATIN AUROBINDO TABLET, FILM COATED 20MG	484/23T	484/23T	AUROBINDO PHARMA (MALTA) 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)*
ATORVASTATIN AUROBINDO TABLET, FILM COATED 40MG	483/23T	483/23T	AUROBINDO PHARMA (MALTA) 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)*
MULTIBIC POTASSIUM-FREE SOLUTION FOR HAEMOFILTRATION	2046/23T, 2047/23T	2046/23T, 2047/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND 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.III.1.a.2

				B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MULTIBIC POTASSIUM SOLUTION FOR HAEMOFILTRATION 2mmol/L	2044/23T, 2045/23T	2044/23T, 2045/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND 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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated

				Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MULTIBIC POTASSIUM SOLUTION FOR HAEMOFILTRATION 3mmol/L	2042/23T, 2043/23T	2042/23T, 2043/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND 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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MULTIBIC POTASSIUM SOLUTION FOR HAEMOFILTRATION 4mmol/L	2040/23T, 2041/23T	2040/23T, 2041/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND 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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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	9886/22T	9886/22T	TAD PHARMA 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)
TICABRIL TABLET, FILM COATED 90MG	9885/22T	9885/22T	TAD PHARMA 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)
OLANZAPINE AUROBINDO TABLET 5MG	784/23T	784/23T	AUROBINDO PHARMA (MALTA) LIMITED	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
OLANZAPINE AUROBINDO TABLET 10MG	783/23T	783/23T	AUROBINDO PHARMA (MALTA) LIMITED	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
LETYBO POWDER FOR SOLUTION FOR INJECTION 50U	2526/23T	2526/23T	CROMA-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
OLANZAPINE AUROBINDO TABLET 5MG	796/23T	796/23T	AUROBINDO PHARMA (MALTA) 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
OLANZAPINE AUROBINDO TABLET 10MG	795/23T	795/23T	AUROBINDO PHARMA (MALTA) 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
LOGNIF CAPSULE, HARD 0.5MG	2627/23T	2627/23T	TEVA 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
ROZOR TABLET, FILM COATED 10MG/10MG	1283/23T	1283/23T	VIATRIS HEALTHCARE LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ROZOR TABLET, FILM COATED 20MG/10MG	1282/23T	1282/23T	VIATRIS HEALTHCARE LIMITED.	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	9611/22T	9611/22T	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
YASMIN TABLET, FILM COATED 0.03MG/3MG	9612/22T	9612/22T	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
CELMANTIN TABLET, FILM COATED 10MG	2508/23T, 2509/23T, 2510/23T, 2511/23T, 2512/23T, 2513/23T, 2514/23T, 2515/23T, 2516/23T	2508/23T, 2509/23T, 2510/23T, 2511/23T, 2512/23T, 2513/23T, 2514/23T, 2515/23T, 2516/23T	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
CELMANTIN TABLET, FILM COATED 5MG	2517/23T, 2518/23T, 2519/23T, 2520/23T, 2521/23T, 2522/23T, 2523/23T, 2524/23T, 2525/23T	2517/23T, 2518/23T, 2519/23T, 2520/23T, 2521/23T, 2522/23T, 2523/23T, 2524/23T, 2525/23T	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
CELMANTIN TABLET, FILM COATED 20MG	2499/23T, 2500/23T, 2501/23T, 2502/23T, 2503/23T, 2504/23T, 2505/23T, 2506/23T, 2507/23T	2499/23T, 2500/23T, 2501/23T, 2502/23T, 2503/23T, 2504/23T, 2505/23T, 2506/23T, 2507/23T	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
CELMANTIN TABLET, FILM COATED 40MG	2490/23T, 2491/23T, 2492/23T, 2493/23T, 2494/23T, 2495/23T, 2496/23T, 2497/23T, 2498/23T	2490/23T, 2491/23T, 2492/23T, 2493/23T, 2494/23T, 2495/23T, 2496/23T, 2497/23T, 2498/23T	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
SEVOFLURANE-PIRAMAL INHALATION VAPOUR, LIQUID 100% V/V	1919/23T	1919/23T	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
INFLUVAC SUB-UNIT TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	2307/23T	2307/23T	VIATRIS HEALTHCARE LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 5MG/100ML	1233/23T	1233/23T	ALTAN PHARMACEUTICALS 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
FENODEX TABLET, FILM COATED 12.5MG	955/23T	955/23T	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)
FENODEX TABLET, FILM COATED 25MG	954/23T	954/23T	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)
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	1410/23T	1410/23T	ASTELLAS PHARMACEUTICALS A.E.B.E.	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
OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	2318/23T	2318/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	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	9895/22T, 9896/22T, 9897/22T, 9898/22T, 9899/22T, 9900/22T, 9901/22T, 9902/22T, 9903/22T	9895/22T, 9896/22T, 9897/22T, 9898/22T, 9899/22T, 9900/22T, 9901/22T, 9902/22T, 9903/22T	GE HEALTHCARE AS	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific B.II.b.1.z B.II.b.1.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufac B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test proce B.II.d.2.a B.II.d.2.a

				- QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test proce B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specif B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - 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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 4000IU	2951/23T	2951/23T	VENIPHARM	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	2952/23T	2952/23T	VENIPHARM	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 6000IU	2955/23T	2955/23T	VENIPHARM	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 10000IU	2953/23T	2953/23T	VENIPHARM	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 8000IU	2954/23T	2954/23T	VENIPHARM	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
NICORETTE QUICKSPRAY OROMUCOSAL SPRAY, SOLUTION 1MG/DOSE	1104/23T	1104/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	1106/23T	1106/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing

				authorisation holder
IMODIUM PLUS TABLET 2MG/125MG	1105/23T	1105/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PROGRAF CAPSULE, HARD 5MG	110/23T, 111/23T, 112/23T	110/23T, 111/23T, 112/23T	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.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
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	107/23T, 108/23T, 109/23T	107/23T, 108/23T, 109/23T	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.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
PROGRAF CAPSULE, HARD 1MG	104/23T, 105/23T, 106/23T	104/23T, 105/23T, 106/23T	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.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
PROGRAF CAPSULE, HARD 0.5MG	113/23T, 114/23T, 115/23T	113/23T, 114/23T, 115/23T	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.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
AUGMENTIN MIXED FRUIT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	544/23T	544/23T	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
RISPERDAL CONSTA POWDER & SOLVENT FOR PROLONGED RELEASE SUSPENION FOR INJECTION 25MG/VIAL	1610/23T	1610/23T	JANSSEN-CILAG INTERNATIONAL NV	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
RISPERDAL CONSTA POWDER & SOLVENT FOR PROLONGED RELEASE SUSPENION FOR INJECTION 37.5MG/VIAL	1609/23T	1609/23T	JANSSEN-CILAG INTERNATIONAL NV	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
RISPERDAL CONSTA POWDER & SOLVENT FOR PROLONGED RELEASE SUSPENION FOR INJECTION 50MG/VIAL	1608/23T	1608/23T	JANSSEN-CILAG INTERNATIONAL NV	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
ATACAND TABLET 4MG	8997/22T, 8998/22T, 8999/22T, 9000/22T, 9001/22T, 9002/22T, 9003/22T	8997/22T, 8998/22T, 8999/22T, 9000/22T, 9001/22T, 9002/22T, 9003/22T	CHEPLAPHARM ARZNEIMITTEL GMBH.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, 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 - 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 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 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.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control 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
ATACAND TABLET 32MG	8974/22T, 8975/22T, 8976/22T, 8977/22T, 8978/22T, 8979/22T, 8980/22T, 8981/22T	8974/22T, 8975/22T, 8976/22T, 8977/22T, 8978/22T, 8979/22T, 8980/22T, 8981/22T	CHEPLAPHARM ARZNEIMITTEL GMBH.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, 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 - 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 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 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.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control 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
ATACAND TABLET 16MG	8982/22T, 8983/22T, 8984/22T, 8985/22T, 8986/22T, 8987/22T, 8988/22T, 8989/22T	8982/22T, 8983/22T, 8984/22T, 8985/22T, 8986/22T, 8987/22T, 8988/22T, 8989/22T	CHEPLAPHARM ARZNEIMITTEL GMBH.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, 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 - 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 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 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.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control 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
ATACAND TABLET 8MG	8990/22T, 8991/22T, 8992/22T, 8993/22T, 8994/22T, 8995/22T, 8996/22T	8990/22T, 8991/22T, 8992/22T, 8993/22T, 8994/22T, 8995/22T, 8996/22T	CHEPLAPHARM ARZNEIMITTEL GMBH.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, 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 - 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 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 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.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control 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
KETIPINE TABLET, FILM COATED 25MG	9480/22T, 9481/22T, 9482/22T, 9483/22T, 9484/22T	9480/22T, 9481/22T, 9482/22T, 9483/22T, 9484/22T	VIANEX 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.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 ap B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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.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
KETIPINE TABLET, FILM COATED 300MG	9465/22T, 9466/22T, 9467/22T, 9468/22T, 9469/22T	9465/22T, 9466/22T, 9467/22T, 9468/22T, 9469/22T	VIANEX 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.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 ap B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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.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
KETIPINE TABLET, FILM COATED 100MG	9475/22T, 9476/22T, 9477/22T, 9478/22T, 9479/22T	9475/22T, 9476/22T, 9477/22T, 9478/22T, 9479/22T	VIANEX 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.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 ap B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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.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
KETIPINE TABLET, FILM COATED 200MG	9470/22T, 9471/22T, 9472/22T, 9473/22T, 9474/22T	9470/22T, 9471/22T, 9472/22T, 9473/22T, 9474/22T	VIANEX 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.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 ap B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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.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
DUOKOPT EYE DROPS, SOLUTION 20MG/ML+5MG/ML	884/23T, 885/23T, 886/23T	884/23T, 885/23T, 886/23T	LABORATOIRES THEA	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 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
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	2019/23T	2019/23T	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	2013/23T	2013/23T	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	2015/23T	2015/23T	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	2020/23T	2020/23T	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	2012/23T	2012/23T	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	2016/23T	2016/23T	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	2018/23T	2018/23T	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	2017/23T	2017/23T	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	2014/23T	2014/23T	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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 4000IU	427/23T	427/23T	VENIPHARM	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.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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 2000IU	426/23T	426/23T	VENIPHARM	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.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

LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 6000IU	430/23T	430/23T	VENIPHARM	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.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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 10000IU	428/23T	428/23T	VENIPHARM	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.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/immunol ogical medicinal product and the change requires an assessment of comparability
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 8000IU	429/23T	429/23T	VENIPHARM	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.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/immunol ogical medicinal product and the change requires an assessment of comparability
STOVADIS TABLET, FILM COATED 25MG/5MG	9800/22T, 9801/22T	9800/22T, 9801/22T	LES LABORATOIRES SERVIER	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
STOVADIS TABLET, FILM COATED 12.5MG/7.5MG	9802/22T, 9803/22T	9802/22T, 9803/22T	LES LABORATOIRES SERVIER	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
STOVADIS TABLET, FILM COATED 25MG/7.5MG	9804/22T, 9805/22T	9804/22T, 9805/22T	LES LABORATOIRES SERVIER	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
STOVADIS TABLET, FILM COATED 12.5MG/5MG	9806/22T, 9807/22T	9806/22T, 9807/22T	LES LABORATOIRES SERVIER	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
STOVADIS TABLET, FILM COATED 6.25MG/7.5MG	9808/22T, 9809/22T	9808/22T, 9809/22T	LES LABORATOIRES SERVIER	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
STOVADIS TABLET, FILM COATED 6.25MG/5MG	9810/22T, 9811/22T	9810/22T, 9811/22T	LES LABORATOIRES SERVIER	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
VAXIGRIPTETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	929/23T, 930/23T	929/23T, 930/23T	SANOFI PASTEUR.	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
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	931/23T, 932/23T	931/23T, 932/23T	SANOFI PASTEUR.	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
AVAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 160 ANTIGEN UNITS/0.5ML	927/23T, 928/23T	927/23T, 928/23T	SANOFI PASTEUR.	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
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	933/23T, 934/23T	933/23T, 934/23T	SANOFI PASTEUR.	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
HOLESTATIN TABLET, FILM COATED 20MG	1446/23T, 1447/23T	1446/23T, 1447/23T	DEMO 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*
HOLESTATIN TABLET, FILM COATED 10MG	1448/23T, 1449/23T	1448/23T, 1449/23T	DEMO 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*
HOLESTATIN TABLET, FILM COATED 5MG	1450/23T, 1451/23T	1450/23T, 1451/23T	DEMO 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*

XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	1824/23T	1824/23T	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	1823/23T	1823/23T	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 200 UNITS	1822/23T	1822/23T	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
ARCOXIA TABLET, FILM COATED 90MG	1008/23T	1008/23T	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	1011/23T	1011/23T	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	1009/23T	1009/23T	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	1013/23T	1013/23T	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	1017/23T	1017/23T	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/40MG	1019/23T	1019/23T	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	1020/23T	1020/23T	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	1018/23T	1018/23T	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	1021/23T	1021/23T	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EZETROL TABLET 10MG	1015/23T	1015/23T	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	1006/23T	1006/23T	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	1010/23T	1010/23T	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	1007/23T	1007/23T	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	1022/23T	1022/23T	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	1016/23T	1016/23T	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	1014/23T	1014/23T	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	1012/23T	1012/23T	N.V. ORGANON	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MAYMETSI TABLET, FILM COATED 50MG/1000MG	380/23T, 381/23T	380/23T, 381/23T	TAD PHARMA GMBH	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.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
MAYMETSI TABLET, FILM COATED 50MG/850MG	378/23T, 379/23T	378/23T, 379/23T	TAD PHARMA GMBH	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.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
QUELORAN TABLET, PROLONGED-RELEASE 200MG	1230/23T	1230/23T	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
QUELORAN TABLET, PROLONGED-RELEASE 50MG	1232/23T	1232/23T	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
QUELORAN TABLET, PROLONGED-RELEASE 400MG	1228/23T	1228/23T	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
QUELORAN TABLET, PROLONGED-RELEASE 150MG	1231/23T	1231/23T	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

QUELORAN TABLET, PROLONGED-RELEASE 300MG	1229/23T	1229/23T	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
FOSRENOL TABLET, CHEWABLE 500MG	1433/23T	1433/23T	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FOSRENOL TABLET, CHEWABLE 750MG	1434/23T	1434/23T	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PROPESS VAGINAL DELIVERY SYSTEM 10MG/UNIT	9888/22T	9888/22T	FERRING HELLAS MEPE	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)

DEXMEDETOMIDINE/BAXTER CONCENTRATE FOR SOLUTION FOR INFUSION 100MCG/ML	877/23T, 878/23T	877/23T, 878/23T	BAXTER HOLDING B.V.	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
PRORAMACE CAPSULE, HARD 2.5MG/2.5MG	1306/23T, 1307/23T	1306/23T, 1307/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
PRORAMACE CAPSULE, HARD 5MG/2.5MG	1304/23T, 1305/23T	1304/23T, 1305/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
PRORAMACE CAPSULE, HARD 10MG/10MG	1298/23T, 1299/23T	1298/23T, 1299/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
PRORAMACE CAPSULE, HARD 2.5MG/1.25MG	1308/23T, 1309/23T	1308/23T, 1309/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
PRORAMACE CAPSULE, HARD 5MG/5MG	1302/23T, 1303/23T	1302/23T, 1303/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
PRORAMACE CAPSULE, HARD 10MG/5MG	1300/23T, 1301/23T	1300/23T, 1301/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 50U	1826/23T	1826/23T	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	1825/23T	1825/23T	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
AMINOPLASMAL B. BRAUN 10% E SOLUTION FOR INFUSION 100G/L	1631/23T, 1632/23T, 1633/23T, 1634/23T, 1635/23T, 1636/23T	1631/23T, 1632/23T, 1633/23T, 1634/23T, 1635/23T, 1636/23T	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 - 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
OLARTAN-PLUS TABLET, FILM COATED 20MG/25MG	199/23T, 200/23T, 201/23T, 202/23T, 203/23T, 204/23T, 205/23T, 206/23T	199/23T, 200/23T, 201/23T, 202/23T, 203/23T, 204/23T, 205/23T, 206/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG 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 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
OLARTAN-PLUS TABLET, FILM COATED 40MG/25MG	175/23T, 176/23T, 177/23T, 178/23T, 179/23T, 180/23T, 181/23T, 182/23T	175/23T, 176/23T, 177/23T, 178/23T, 179/23T, 180/23T, 181/23T, 182/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG 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

				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
OLARTAN-PLUS TABLET, FILM COATED 40MG/12.5MG	183/23T, 184/23T, 185/23T, 186/23T, 187/23T, 188/23T, 189/23T, 190/23T	183/23T, 184/23T, 185/23T, 186/23T, 187/23T, 188/23T, 189/23T, 190/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG 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 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
OLARTAN-PLUS TABLET, FILM COATED 20MG/12.5MG	191/23T, 192/23T, 193/23T, 194/23T, 195/23T, 196/23T, 197/23T, 198/23T	191/23T, 192/23T, 193/23T, 194/23T, 195/23T, 196/23T, 197/23T, 198/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG 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 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
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/VIAL (100IU/ML)	1913/23T, 1914/23T	1913/23T, 1914/23T	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
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/VIAL(100IU/ML)	1911/23T, 1912/23T	1911/23T, 1912/23T	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
IMIGRAN TABLET, FILM COATED 50MG	8680/22T	8680/22T	GLAXOSMITHKLINE (IRELAND) LIMITED	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.
STREPFEN DIRECT HONEY & LEMON OROMUCOSAL SPRAY, SOLUTION 8.75MG	945/23T, 946/23T, 947/23T	945/23T, 946/23T, 947/23T	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)
WELLBUTRIN XR MODIFIED-RELEASE TABLET 150MG	9179/22T, 9180/22T, 9181/22T, 9182/22T	9179/22T, 9180/22T, 9181/22T, 9182/22T	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. C 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)*
WELLBUTRIN XR MODIFIED-RELEASE TABLET 300MG	9175/22T, 9176/22T, 9177/22T, 9178/22T	9175/22T, 9176/22T, 9177/22T, 9178/22T	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. C 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
OLIMEL N7 EMULSION FOR INFUSION	8415/22T, 8416/22T, 8417/22T, 8418/22T, 8419/22T, 8420/22T, 8421/22T	8415/22T, 8416/22T, 8417/22T, 8418/22T, 8419/22T, 8420/22T, 8421/22T	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 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.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
OLIMEL N12E EMULSION FOR INFUSION	8422/22T, 8423/22T, 8424/22T, 8425/22T, 8426/22T, 8427/22T, 8428/22T	8422/22T, 8423/22T, 8424/22T, 8425/22T, 8426/22T, 8427/22T, 8428/22T	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 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.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
OLIMEL N9 EMULSION FOR INFUSION	8408/22T, 8409/22T, 8410/22T, 8411/22T, 8412/22T, 8413/22T, 8414/22T	8408/22T, 8409/22T, 8410/22T, 8411/22T, 8412/22T, 8413/22T, 8414/22T	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 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.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
OLIMEL PERI N4E EMULSION FOR INFUSION	8443/22T, 8444/22T, 8445/22T, 8446/22T, 8447/22T, 8448/22T, 8449/22T	8443/22T, 8444/22T, 8445/22T, 8446/22T, 8447/22T, 8448/22T, 8449/22T	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 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.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
OLIMEL N7E EMULSION FOR INFUSION	8436/22T, 8437/22T, 8438/22T, 8439/22T,	8436/22T, 8437/22T, 8438/22T, 8439/22T,	BAXTER (HELLAS) EPE	B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE

	8440/22T, 8441/22T, 8442/22T	8440/22T, 8441/22T, 8442/22T		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.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
OLIMEL N9E EMULSION FOR INFUSION	8429/22T, 8430/22T, 8431/22T, 8432/22T, 8433/22T, 8434/22T, 8435/22T	8429/22T, 8430/22T, 8431/22T, 8432/22T, 8433/22T, 8434/22T, 8435/22T	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 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.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
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 250MCG/10MCG	1385/23T	1385/23T	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	1386/23T	1386/23T	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	1387/23T	1387/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MOLAXOLE POWDER FOR ORAL SOLUTION	2011/23T	2011/23T	VIATRIS HEALTHCARE LIMITED.	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)
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 50U	1843/23T	1843/23T	MERZ PHARMACEUTICALS GMBH	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
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 100U	1842/23T	1842/23T	MERZ PHARMACEUTICALS GMBH	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
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/VIAL (100IU/ML)	9856/22T	9856/22T	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
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/VIAL(100IU/ML)	9855/22T	9855/22T	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
PARACETAMOL/KABI SOLUTION FOR INFUSION 10MG/ML	943/23T	943/23T	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)
AMBRISENTAN ACCORD TABLET, FILM COATED 10MG	1490/23T	1490/23T	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
AMBRISENTAN ACCORD TABLET, FILM COATED 5MG	1491/23T	1491/23T	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
REGAINE WOMEN'S FOAM CUTANEOUS FOAM 5% W/W	9238/22T	9238/22T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
OLIMEL N9E EMULSION FOR INFUSION	9166/22T, 9167/22T, 9168/22T	9166/22T, 9167/22T, 9168/22T	BAXTER (HELLAS) EPE	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
OLIMEL N9E EMULSION FOR INFUSION	9166/22T, 9167/22T, 9168/22T	9166/22T, 9167/22T, 9168/22T	BAXTER (HELLAS) EPE	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
OLIMEL N7E EMULSION FOR INFUSION	9169/22T, 9170/22T, 9171/22T	9169/22T, 9170/22T, 9171/22T	BAXTER (HELLAS) EPE	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
OLIMEL N7E EMULSION FOR INFUSION	9169/22T, 9170/22T, 9171/22T	9169/22T, 9170/22T, 9171/22T	BAXTER (HELLAS) EPE	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active

				substance - Other variation
OLIMEL PERI N4E EMULSION FOR INFUSION	9172/22T, 9173/22T, 9174/22T	9172/22T, 9173/22T, 9174/22T	BAXTER (HELLAS) EPE	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
OLIMEL PERI N4E EMULSION FOR INFUSION	9172/22T, 9173/22T, 9174/22T	9172/22T, 9173/22T, 9174/22T	BAXTER (HELLAS) EPE	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
OLIMEL N12E EMULSION FOR INFUSION	9163/22T, 9164/22T, 9165/22T	9163/22T, 9164/22T, 9165/22T	BAXTER (HELLAS) EPE	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
OLIMEL N12E EMULSION FOR INFUSION	9163/22T, 9164/22T, 9165/22T	9163/22T, 9164/22T, 9165/22T	BAXTER (HELLAS) EPE	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
DYMISTA NASAL SPRAY, SUSPENSION	1497/23T	1497/23T	MEDA PHARMACEUTICALS 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
TAFLOTAN EYE DROPS, SOLUTION 15MCG/ML	1224/23T	1224/23T	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)*
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/VIAL	982/23T	982/23T	SEACROSS PHARMA (EUROPE) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PEMETREXED SEACROSS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 500MG/VIAL	981/23T	981/23T	SEACROSS PHARMA (EUROPE) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPTRUZET TABLET, FILM COATED 10MG/40MG	1869/23T, 1870/23T, 1871/23T	1869/23T, 1870/23T, 1871/23T	N.V. ORGANON	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.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
LIPTRUZET TABLET, FILM COATED 10MG/20MG	1872/23T, 1873/23T, 1874/23T	1872/23T, 1873/23T, 1874/23T	N.V. ORGANON	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.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
LIPTRUZET TABLET, FILM COATED 10MG/80MG	1866/23T, 1867/23T, 1868/23T	1866/23T, 1867/23T, 1868/23T	N.V. ORGANON	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.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
LIPTRUZET TABLET, FILM COATED 10MG/10MG	1875/23T, 1876/23T, 1877/23T	1875/23T, 1876/23T, 1877/23T	N.V. ORGANON	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.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
ARESTON TABLET, FILM COATED 12.5MG	8069/22T	8069/22T	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

BALANCE 4.25% GLUCOSE, 1.25MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	1736/23T	1736/23T	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, 1.25MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	1737/23T	1737/23T	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	1735/23T	1735/23T	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	1754/23T	1754/23T	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	1752/23T	1752/23T	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 4.25% GLUCOSE, 1.75MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	1753/23T	1753/23T	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
DELTIUS ORAL DROPS SOLUTION 10000IU/ML	1435/23T	1435/23T	ITF HELLAS A.E.	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
RISPERIDONE AUROBINDO TABLET, FILM COATED 1MG	1571/23T	1571/23T	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
RISPERIDONE AUROBINDO TABLET, FILM COATED 2MG	1570/23T	1570/23T	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
RISPERIDONE AUROBINDO TABLET, FILM COATED 4MG	1568/23T	1568/23T	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
RISPERIDONE AUROBINDO TABLET, FILM COATED 3MG	1569/23T	1569/23T	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
ARIMIDEX TABLET, FILM COATED 1MG	121/23T	121/23T	LABORATOIRES JUVISE	A.7 A.7 - ADMINISTRATIVE CHANGES -

			PHARMACEUTICALS	Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SIRANALEN CAPSULE, HARD 75MG	7700/22T	7700/22T	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
SIRANALEN CAPSULE, HARD 150MG	7699/22T	7699/22T	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
SIRANALEN CAPSULE, HARD 300MG	7698/22T	7698/22T	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
ESMOBETA SOLUTION FOR INFUSION 10MG/ML	732/23T, 1139/23T	732/23T, 1139/23T	NORIDEM ENTERPRISES 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)

ESMOBETA SOLUTION FOR INJECTION 10MG/ML	731/23T, 1138/23T	731/23T, 1138/23T	NORIDEM ENTERPRISES 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)
PADLAS TABLET 50MG	9055/22T	9055/22T	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
LAMIVUDINE/ZIDOVUDINE AUROBINDO TABLET, FILM COATED 150MG/300MG	8583/22T	8583/22T	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
OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	8580/22T	8580/22T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	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.
TRIATEC TABLET 5MG	773/23T	773/23T	SANOFI WINTHROP INDUSTRIE.	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
TRIATEC TABLET 2.5MG	774/23T	774/23T	SANOFI WINTHROP INDUSTRIE.	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
ZANERIL TABLET, FILM COATED 10MG/10MG	666/23T	666/23T	RECORDATI HELLAS PHARMACEUTICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZANERIL TABLET, FILM COATED 20MG/20MG	664/23T	664/23T	RECORDATI HELLAS PHARMACEUTICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZANERIL TABLET, FILM COATED 20MG/10MG	665/23T	665/23T	RECORDATI HELLAS PHARMACEUTICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VAXIGRIPTETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	9236/22T	9236/22T	SANOFI PASTEUR.	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
ENCAPIA TABLET, FILM COATED 200MG	466/23T, 467/23T	466/23T, 467/23T	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)*
LIPOCAT TABLET, FILM COATED 10MG/80MG	414/23T	414/23T	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)
LIPOCAT TABLET, FILM COATED 10MG/10MG	417/23T	417/23T	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)
LIPOCAT TABLET, FILM COATED 10MG/20MG	416/23T	416/23T	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)
LIPOCAT TABLET, FILM COATED 10MG/40MG	415/23T	415/23T	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)
VALGANCICLOVIR ACCORD TABLET, FILM COATED 450MG	1089/23T, 1090/23T, 1091/23T	1089/23T, 1090/23T, 1091/23T	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 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.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

DEMOLOX POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG/VIAL	1056/23T	1056/23T	NORIDEM ENTERPRISES 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)
CITRAFLEET POWDER FOR ORAL SOLUTION	730/23T	730/23T	CASEN RECORDATI SL	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
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	1045/23T	1045/23T	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	1048/23T	1048/23T	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	1046/23T	1046/23T	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	1047/23T	1047/23T	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
ATORVASTATIN KRKA TABLET, FILM COATED 20MG	376/23T	376/23T	KRKA D.D. NOVO MESTO	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
ATORVASTATIN KRKA TABLET, FILM COATED 10MG	377/23T	377/23T	KRKA D.D. NOVO MESTO	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
ATORVASTATIN KRKA TABLET, FILM COATED 40MG	375/23T	375/23T	KRKA D.D. NOVO MESTO	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

SALMETEROL + FLUTICASONE/MYLAN PRESSURISED INHALATION, SUSPENSION 25MCG/250MCG	2374/23T	2374/23T	VIATRIS LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SALMETEROL + FLUTICASONE/MYLAN PRESSURISED INHALATION, SUSPENSION 25MCG/125MCG	2375/23T	2375/23T	VIATRIS LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 15MG/1.5ML	3015/22T	3015/22T	NOVO NORDISK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	3016/22T	3016/22T	NOVO NORDISK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	3017/22T	3017/22T	NOVO NORDISK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	3018/22T	3018/22T	NOVO NORDISK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 10MG/1.5ML	3014/22T	3014/22T	NOVO NORDISK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Implementation of QRD template
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	3019/22T	3019/22T	NOVO NORDISK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	3021/22T	3021/22T	NOVO NORDISK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	3020/22T	3020/22T	NOVO NORDISK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
NORDITROPIN SIMPLEXx SOLUTION FOR INJECTION 5MG/1.5ML	3013/22T	3013/22T	NOVO NORDISK A/S	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
ORIENS VOM TABLET, SUBLINGUAL 50MG	630/23T	630/23T	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
AMOXIL FORTE POWDER FOR ORAL SUSPENSION 250MG/5ML	1179/23T, 1180/23T	1179/23T, 1180/23T	GLAXOSMITHKLINE (IRELAND) 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
RAPIBLOC CONCENTRATE FOR SOLUTION FOR INJECTION 20MG/2ML	353/23T	353/23T	AMOMED 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 -
RAPIBLOC POWDER FOR SOLUTION FOR INFUSION 300MG/VIAL	352/23T	352/23T	AMOMED 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 -
FERINJECT DISPERSION FOR INJECTION/INFUSION 50MG IRON/ML	6569/22T	6569/22T	VIFOR FRANCE	C.I.z C.I.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
AVELOX TABLET, FILM COATED 400MG	1331/23T, 1332/23T	1331/23T, 1332/23T	BAYER HELLAS ABEE	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	1424/23T	1424/23T	PHARMASCIENCE INTERNATIONAL 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
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 10MG	1423/23T	1423/23T	PHARMASCIENCE INTERNATIONAL 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
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 25MG	1421/23T	1421/23T	PHARMASCIENCE INTERNATIONAL 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
LENALIDOMIDE PHARMASCIENCE CAPSULE, HARD 15MG	1422/23T	1422/23T	PHARMASCIENCE INTERNATIONAL 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
FERINJECT DISPERSION FOR INJECTION/INFUSION 50MG IRON/ML	9714/22T, 9715/22T, 9716/22T	9714/22T, 9715/22T, 9716/22T	VIFOR FRANCE	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 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
TRIATEC TABLET 5MG	2824/23T	2824/23T	SANOFI WINTHROP INDUSTRIE.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites

				for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SIRANALEN ORAL SOLUTION 20MG/ML	7168/22T, 7169/22T, 7170/22T, 7171/22T, 7172/22T, 7173/22T	7168/22T, 7169/22T, 7170/22T, 7171/22T, 7172/22T, 7173/22T	MEDOCHEMIE LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient 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.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.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)
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	3018/23T	3018/23T	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
DUODART CAPSULE, HARD	363/23T	363/23T	GLAXOSMITHKLINE TRADING SERVICES 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)
CIPROFLOXACIN KABI SOLUTION FOR INFUSION 2MG/ML(400MG/200ML)	777/23T	777/23T	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
CIPROFLOXACIN KABI SOLUTION FOR INFUSION 2MG/ML(200MG/100ML)	778/23T	778/23T	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
GABAPENTIN ACCORD CAPSULE, HARD 300MG	881/23T, 882/23T	881/23T, 882/23T	ACCORD HEALTHCARE S.L.U	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
GABAPENTIN ACCORD CAPSULE, HARD 400MG	879/23T, 880/23T	879/23T, 880/23T	ACCORD HEALTHCARE S.L.U	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the

				outcome of 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	1425/23T	1425/23T	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/intermediate used in the manufacturing process of 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	1426/23T	1426/23T	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/intermediate used in the manufacturing process of 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	2940/22T, 2941/22T	2940/22T, 2941/22T	BAUSCH + LOMB 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
LOCERYL MEDICATED NAIL LACQUER 5% (W/V)	1323/23T	1323/23T	GALDERMA INTERNATIONAL ,FRANCE	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
MOLAXOLE POWDER FOR ORAL SOLUTION	9735/22T	9735/22T	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)*
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	9783/22T	9783/22T	NOVO NORDISK A/S	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
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	9780/22T	9780/22T	NOVO NORDISK A/S	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
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	9778/22T	9778/22T	NOVO NORDISK A/S	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
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	9779/22T	9779/22T	NOVO NORDISK A/S	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
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	9782/22T	9782/22T	NOVO NORDISK A/S	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
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	9781/22T	9781/22T	NOVO NORDISK A/S	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
DUOKOPT EYE DROPS, SOLUTION 20MG/ML+5MG/ML	116/23T	116/23T	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
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250/500 (50 IU/ml)	9584/22T, 9585/22T, 9586/22T, 9587/22T, 9588/22T	9584/22T, 9585/22T, 9586/22T, 9587/22T, 9588/22T	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.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.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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 100IU/ML(500IU/5ML)	9574/22T, 9575/22T, 9576/22T, 9577/22T, 9578/22T	9574/22T, 9575/22T, 9576/22T, 9577/22T, 9578/22T	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.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.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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000 (100 IU/ml)	9579/22T, 9580/22T, 9581/22T, 9582/22T, 9583/22T	9579/22T, 9580/22T, 9581/22T, 9582/22T, 9583/22T	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.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.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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 200IU/ML(1000IU/5ML)	9569/22T, 9570/22T, 9571/22T, 9572/22T, 9573/22T	9569/22T, 9570/22T, 9571/22T, 9572/22T, 9573/22T	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.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.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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
FULVESTRANT PHARMASCIENCE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 250MG	944/23T	944/23T	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
AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	1123/23T	1123/23T	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
SOOLANTRA CREAM 10MG/G	290/23T, 291/23T	290/23T, 291/23T	GALDERMA INTERNATIONAL ,FRANCE	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)*
EPIDUO FORTE GEL 0.3%/2.5%	292/23T, 293/23T	292/23T, 293/23T	GALDERMA INTERNATIONAL ,FRANCE	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)*
EPIDUO GEL (0.001G/0.025G)G	294/23T, 295/23T	294/23T, 295/23T	GALDERMA INTERNATIONAL ,FRANCE	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)*
VEZIMED TABLET, FILM COATED 10MG	1029/23T	1029/23T	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
VEZIMED TABLET, FILM COATED 5MG	1030/23T	1030/23T	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
SANDIMMUN NEORAL CAPSULE, SOFT 100MG	1113/23T	1113/23T	NOVARTIS IRELAND LIMITED	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
SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML	1112/23T	1112/23T	NOVARTIS IRELAND LIMITED	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
SANDIMMUN NEORAL CAPSULE, SOFT 50MG	1114/23T	1114/23T	NOVARTIS IRELAND LIMITED	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

SANDIMMUN NEORAL CAPSULE, SOFT 25MG	1115/23T	1115/23T	NOVARTIS IRELAND LIMITED	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
LETYBO POWDER FOR SOLUTION FOR INJECTION 50U	991/23T	991/23T	CROMA-PHARMA GMBH	B.I.z B.I.z - Quality change - Active substance - Other variation
DEFERASIROX MSN TABLET, FILM COATED 360MG	8163/22T	8163/22T	MSN LABS EUROPE 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)
DEFERASIROX MSN TABLET, FILM COATED 180MG	8164/22T	8164/22T	MSN LABS EUROPE 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)
DEFERASIROX MSN TABLET, FILM COATED 90MG	8165/22T	8165/22T	MSN LABS EUROPE 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)
CONTROLOC IV POWDER FOR SOLUTION FOR INJECTION 40MG	9712/22T, 9713/22T	9712/22T, 9713/22T	MUNDIPHARMA 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MYELOMIDE CAPSULE, HARD 25MG	2433/22T	2433/22T	ANABIOSIS PC.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics,

				Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MYELOMIDE CAPSULE, HARD 10MG	2431/22T	2431/22T	ANABIOSIS PC.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MYELOMIDE CAPSULE, HARD 5MG	2430/22T	2430/22T	ANABIOSIS PC.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference

				product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MYELOMIDE CAPSULE, HARD 15MG	2432/22T	2432/22T	ANABIOSIS PC.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 4MG	9359/22T	9359/22T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 1MG	9362/22T	9362/22T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 2MG	9361/22T	9361/22T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 3MG	9360/22T	9360/22T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the

				name and/or address of the marketing authorisation holder
AFITEN TABLET 10MG	9087/22T	9087/22T	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
AFITEN TABLET 5MG	9086/22T	9086/22T	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
LOBIVON TABLET 5MG	1227/23T	1227/23T	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
CIPROFLOXACIN KABI SOLUTION FOR INFUSION 2MG/ML(400MG/200ML)	722/23T	722/23T	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
CIPROFLOXACIN KABI SOLUTION FOR INFUSION 2MG/ML(200MG/100ML)	723/23T	723/23T	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
BENDAMUSTIN LEDPHARM POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 2.5MG/ML	1225/23T	1225/23T	O.S.K. LEDPHARM LTD	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
CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	1050/23T	1050/23T	VIATRIS HEALTHCARE 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
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	1049/23T	1049/23T	VIATRIS HEALTHCARE 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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 4000IU	8216/22T, 8217/22T, 8218/22T, 8219/22T	8216/22T, 8217/22T, 8218/22T, 8219/22T	VENIPHARM	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 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.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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 2000IU	8211/22T, 8212/22T, 8213/22T, 8214/22T	8211/22T, 8212/22T, 8213/22T, 8214/22T	VENIPHARM	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 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.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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 8000IU	8201/22T, 8202/22T, 8203/22T, 8204/22T	8201/22T, 8202/22T, 8203/22T, 8204/22T	VENIPHARM	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 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.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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 10000IU	8196/22T, 8197/22T, 8198/22T, 8199/22T	8196/22T, 8197/22T, 8198/22T, 8199/22T	VENIPHARM	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 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.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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 6000IU	8206/22T, 8207/22T, 8208/22T, 8209/22T	8206/22T, 8207/22T, 8208/22T, 8209/22T	VENIPHARM	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 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.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
SALOFALK SUPPOSITORY 1G	867/23T	867/23T	DR. FALK 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
SALOFALK TABLET, GASTRO-RESISTANT 1G	868/23T	868/23T	DR. FALK 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
ACTILYSE POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1MG/ML	1289/23T	1289/23T	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
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	1372/23T	1372/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	1370/23T	1370/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	1371/23T	1371/23T	MUNDIPHARMA PHARMACEUTICALS LTD	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	1369/23T	1369/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	1384/23T	1384/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	1383/23T	1383/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	1382/23T	1382/23T	MUNDIPHARMA PHARMACEUTICALS LTD	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	1381/23T	1381/23T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ACNATAC GEL	9770/22T	9770/22T	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
ACNATAC GEL	9344/22T	9344/22T	VIATRIS HEALTHCARE LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 250MCG/10MCG	9789/22T	9789/22T	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	9790/22T	9790/22T	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	9791/22T	9791/22T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AKTIPROL TABLET 100MG	9631/22T	9631/22T	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
AKTIPROL TABLET 200MG	9630/22T	9630/22T	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
AKTIPROL TABLET 400MG	9629/22T	9629/22T	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

AKTIPROL TABLET 50MG	9632/22T	9632/22T	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
PHYSIONEAL 40 GLUCOSE 3.86% W/V/38.6MG/ML CLEAR-FLEX SOLUTION FOR PERITONEAL DIALYSIS 3.86%	9651/22T	9651/22T	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	9652/22T	9652/22T	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	9655/22T	9655/22T	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	9656/22T	9656/22T	BAXTER (HELLAS) EPE	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	9654/22T	9654/22T	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE

SOLUTION FOR PERITONEAL DIALYSIS 3.86% W/V				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	9653/22T	9653/22T	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, FILM COATED 20MG	9500/22T, 9501/22T, 9502/22T	9500/22T, 9501/22T, 9502/22T	UPJOHN HELLAS LTD	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.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

LIPITOR TABLET, FILM COATED 10MG	9503/22T, 9504/22T, 9505/22T	9503/22T, 9504/22T, 9505/22T	UPJOHN HELLAS LTD	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.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
LIPITOR TABLET, FILM COATED 40MG	9497/22T, 9498/22T, 9499/22T	9497/22T, 9498/22T, 9499/22T	UPJOHN HELLAS LTD	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.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
ZARATOR TABLET, FILM COATED 10MG	9494/22T, 9495/22T, 9496/22T	9494/22T, 9495/22T, 9496/22T	UPJOHN HELLAS LTD	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.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
ZARATOR TABLET, FILM COATED 20MG	9491/22T, 9492/22T, 9493/22T	9491/22T, 9492/22T, 9493/22T	UPJOHN HELLAS LTD	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.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
ZARATOR TABLET, FILM COATED 40MG	9488/22T, 9489/22T, 9490/22T	9488/22T, 9489/22T, 9490/22T	UPJOHN HELLAS LTD	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.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
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/25MG	9565/22T	9565/22T	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	9568/22T	9568/22T	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	9566/22T	9566/22T	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	9567/22T	9567/22T	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
ALFUZOSIN AUROBINDO TABLET, PROLONGED-RELEASE 10MG	633/23T	633/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
SOFENTIL SOLUTION FOR INJECTION OR INFUSION 5MCG/ML	9759/22T	9759/22T	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)*

SOFENTIL SOLUTION FOR INJECTION OR INFUSION 50MCG/ML	9758/22T	9758/22T	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)*
MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/VIAL	742/23T	742/23T	APTA MEDICA INTERNACIONAL D.O.O.	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)
MEROPENEM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	743/23T	743/23T	APTA MEDICA INTERNACIONAL D.O.O.	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)
LACOSAMIDE FRESENIUS KABI SOLUTION FOR INFUSION 10MG/ML	9382/22T, 9383/22T	9382/22T, 9383/22T	FRESENIUS KABI HELLAS A.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 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
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	9736/22T	9736/22T	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
PARACETAMOL/BAXTER VIAFLO SOLUTION FOR INFUSION 10 MG/ML	446/23T	446/23T	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
NANOGAM SOLUTION FOR INFUSION 100MG/ML	319/23T	319/23T	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	300/23T	300/23T	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	299/23T	299/23T	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
APIXABAN/MYLAN TABLET, FILM COATED 2.5MG	779/23T	779/23T	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
APIXABAN/MYLAN TABLET, FILM COATED 5MG	780/23T	780/23T	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
SALOFALK SUPPOSITORY 1G	9785/22T, 9786/22T	9785/22T, 9786/22T	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
ALBUNORM 20% SOLUTION FOR INFUSION 200G/L	8737/22T	8737/22T	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
ALBUNORM 5% SOLUTION FOR INFUSION 50G/L	8739/22T	8739/22T	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

ALBUNORM 25% SOLUTION FOR INFUSION 250G/L	8736/22T	8736/22T	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
ALBUNORM 4% SOLUTION FOR INFUSION 40G/L	8738/22T	8738/22T	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
DUOMAX TABLET, FILM COATED 500MG/150MG	8351/22T	8351/22T	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 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
FORTUM POWDER FOR SOLUTION FOR INJECTION 1G/VIAL	1330/23T	1330/23T	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
LONATA EYE DROPS, SOLUTION (50MCG/5MG)/ML	703/23T	703/23T	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
DIENOGEST BESINS TABLET 2MG	721/23T	721/23T	LABORATOIRES BESINS INTERNATIONAL	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
EMLA CREAM 5%	1028/23T	1028/23T	ASPEN PHARMA TRADING LIMITED	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)
LIPTRUZET TABLET, FILM COATED 10MG/80MG	8947/22T, 8948/22T, 8949/22T, 8950/22T, 8951/22T	8947/22T, 8948/22T, 8949/22T, 8950/22T, 8951/22T	N.V. ORGANON	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 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.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.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
LECALCIF ORAL SOLUTION 25000IU	1100/23T	1100/23T	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
LECALCIF ORAL SOLUTION 100000IU	1099/23T	1099/23T	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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	9729/22T	9729/22T	SANOFI WINTHROP INDUSTRIE.	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	9731/22T	9731/22T	SANOFI WINTHROP INDUSTRIE.	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	9730/22T	9730/22T	SANOFI WINTHROP INDUSTRIE.	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	9728/22T	9728/22T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the

				marketing authorisation holder
LIBRAX TABLET, COATED 5MG/2.5MG	7817/22T	7817/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
FRAXIPARINE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 2850IU AXa/0.3ML	7798/22T	7798/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
FRAXIPARINE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 5700IU AXa/0.6ML	7799/22T	7799/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BRUFEN TABLET, COATED 400MG	7806/22T	7806/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LEPONEX TABLET 100MG	7816/22T	7816/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LEPONEX TABLET 25MG	7815/22T	7815/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DUPHASTON TABLET, FILM COATED 10MG	7813/22T	7813/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DUPHALAC ORAL SOLUTION 3.335G/5ML	7805/22T	7805/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ROZOR TABLET, FILM COATED 20MG/10MG	7797/22T	7797/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ROZOR TABLET, FILM COATED 10MG/10MG	7796/22T	7796/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BETASERC TABLET, ORODISPERSIBLE 24MG	7809/22T	7809/22T	MYLAN IRE HEALTHCARE LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	8318/22T	8318/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TEVETEN TABLET, FILM COATED 600MG	7812/22T	7812/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LIPIDIL NT TABLET, FILM COATED 145MG	7810/22T	7810/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	7814/22T	7814/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
SYNTOCINON CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTIO 10 IU/ML	7795/22T	7795/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation

DICETEL TABLET, FILM COATED 50MG	7793/22T	7793/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TOBI SOLUTION FOR INHALATION 300MG/5ML	7791/22T	7791/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
FEMOSTON TABLET, FILM COATED	7811/22T	7811/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
RYTHMONORM TABLET, FILM COATED 150MG	7792/22T	7792/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DIFFLAM SPRAY 0.15% W/V	7819/22T	7819/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
FAVERIN TABLET, FILM COATED 50MG	7807/22T	7807/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
BETASERC TABLET 16MG	7818/22T	7818/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ISOPTIN SUSTAINED RELEASE TABLETS 240MG	7790/22T	7790/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ISOPTIN TABLET, FILM COATED 80MG	7788/22T	7788/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ISOPTIN TABLET, FILM COATED 40MG	7789/22T	7789/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DUSPATALIN TABLET, COATED 135MG	7803/22T	7803/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
FAVERIN TABLET, FILM COATED 100MG	7808/22T	7808/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CREON 10000 CAPSULE, HARD 150MG	7794/22T	7794/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PHYSIOTENS TABLET, FILM COATED 0.2MG	7801/22T	7801/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DUSPATALIN RETARD CAPSULE, HARD, PROLONGED-RELEASE 200MG	7804/22T	7804/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PHYSIOTENS TABLET, FILM COATED 0.4MG	7800/22T	7800/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ASACOL TABLET, GASTRO-RESISTANT 400MG	800/23T	800/23T	TILLOTTS 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
ASACOL ENEMA 4G/100ML	801/23T	801/23T	TILLOTTS 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
DELTACEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G/VIAL	673/23T	673/23T	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
DELTACEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	672/23T	672/23T	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
DELTACEF POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	671/23T	671/23T	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
SAPRAX TABLET, FILM COATED 10MG	3236/23T	3236/23T	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
SAPRAX TABLET, FILM COATED 5MG	3237/23T	3237/23T	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
PRIDATON TABLET, FILM COATED 50MG	2555/23T	2555/23T	CODAL-SYNTO LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ATORSTAN TABLET, FILM COATED 40MG	3152/23T	3152/23T	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
ATORSTAN TABLET, FILM COATED 10MG	3154/23T	3154/23T	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
ATORSTAN TABLET, FILM COATED 20MG	3153/23T	3153/23T	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
ATORSTAN TABLET, FILM COATED 80MG	3151/23T	3151/23T	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
STATOL TABLET, FILM COATED 10MG	3066/23T	3066/23T	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
STATOL TABLET, FILM COATED 40MG	3064/23T	3064/23T	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
STATOL TABLET, FILM COATED 5MG	3067/23T	3067/23T	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
STATOL TABLET, FILM COATED 20MG	3065/23T	3065/23T	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
LIPREN TABLET, FILM COATED 10MG	3021/23T	3021/23T	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
LIPREN TABLET, FILM COATED 40MG	3019/23T	3019/23T	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
LIPREN TABLET, FILM COATED 20MG	3020/23T	3020/23T	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
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG	2857/23T	2857/23T	MEDOCHEMIE LTD	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
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G	2858/23T	2858/23T	MEDOCHEMIE LTD	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
DAKTODOR CREAM (2% + 1%) w/w	330/23T, 331/23T, 332/23T	330/23T, 331/23T, 332/23T	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 A.z A.z - ADMINISTRATIVE CHANGES - Change in the nomenclature of the container material for immediate packaging of the finished product 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.
REMABIRAT TABLET, FILM COATED 250MG	9542/22T	9542/22T	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)
REMABIRAT TABLET, FILM COATED 500MG	9541/22T	9541/22T	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)
ISOTROIN CAPSULE, SOFT 30MG	317/23T	317/23T	IASIS PHARMACEUTICALS HELLAS 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
ISOTROIN CAPSULE, SOFT 10MG	316/23T	316/23T	IASIS PHARMACEUTICALS HELLAS 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
ISOTROIN CAPSULE, SOFT 20MG	315/23T	315/23T	IASIS PHARMACEUTICALS HELLAS 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
PRIACIN TABLET, FILM COATED 10MG	2836/23T	2836/23T	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
PRIACIN TABLET, FILM COATED 20MG	2835/23T	2835/23T	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
PRIACIN TABLET, FILM COATED 40MG	2834/23T	2834/23T	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
KLONT TABLET 200MG	9400/22T	9400/22T	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
DEPAKINE CHRONO TABLET, PROLONGED-RELEASE 500MG	2464/23T, 2465/23T	2464/23T, 2465/23T	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)* A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ALLOPURINOL ACCORD TABLET 100MG	9684/21T, 9685/21T, 9686/21T, 9687/21T	9684/21T, 9685/21T, 9686/21T, 9687/21T	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.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 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
ALLOPURINOL ACCORD TABLET 100MG	9790/21T	9790/21T	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
REZAVIR TABLET, FILM COATED 150MG	2066/23T	2066/23T	REMEDICA LTD	C.I.2.z C.I.2.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Other variation
REZAVIR TABLET, FILM COATED 400MG	2064/23T	2064/23T	REMEDICA LTD	C.I.2.z C.I.2.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Other variation
REZAVIR TABLET, FILM COATED 75MG	2067/23T	2067/23T	REMEDICA LTD	C.I.2.z C.I.2.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following

				assessment of the same change for the reference product - Other variation
REZAVIR TABLET, FILM COATED 800MG	2062/23T	2062/23T	REMEDICA LTD	C.I.2.z C.I.2.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Other variation
REZAVIR TABLET, FILM COATED 600MG	2063/23T	2063/23T	REMEDICA LTD	C.I.2.z C.I.2.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Other variation
REZAVIR TABLET, FILM COATED 300MG	2065/23T	2065/23T	REMEDICA LTD	C.I.2.z C.I.2.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a

				generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Other variation
SORIL THROAT SPRAY OROMUCOSAL SPRAY, SOLUTION 1.5MG/ML	2625/23T, 2626/23T	2625/23T, 2626/23T	SAPIENS 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.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
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	2561/22T, 2562/22T	2561/22T, 2562/22T	GLAXOSMITHKLINE BIOLOGICALS SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation 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
AXETINE POWDER FOR SOLUTION FOR INJECTION/INFUSION 1.5G	1958/23T, 1959/23T, 1960/23T	1958/23T, 1959/23T, 1960/23T	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 B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 POWDER FOR SOLUTION FOR INJECTION/INFUSION 250MG/VIAL	1955/23T, 1956/23T, 1957/23T	1955/23T, 1956/23T, 1957/23T	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 B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 POWDER FOR SOLUTION FOR INJECTION/INFUSION 750MG/VIAL	1952/23T, 1953/23T, 1954/23T	1952/23T, 1953/23T, 1954/23T	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 B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.1MG/ML	3956/22T	3956/22T	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 - Change in supplier of sterilised primary container

				components, which are to be used in the aseptic manufacture of medicinal products
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.3MG/ML	3957/22T	3957/22T	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 - Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of medicinal products
EXTRANEAL SOLUTION FOR PERITONEAL DIALYSIS	8885/21T	8885/21T	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)*
EXTRANEAL SOLUTION FOR PERITONEAL DIALYSIS	4541/21T, 4542/21T, 6425/21T	4541/21T, 4542/21T, 6425/21T	BAXTER (HELLAS) EPE	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation 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
LENALIDOMIDE GRINDEKS CAPSULE, HARD 2.5MG	1145/22T	1145/22T	AS GRINDEKS	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LENALIDOMIDE GRINDEKS CAPSULE, HARD 5MG	1146/22T	1146/22T	AS GRINDEKS	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LENALIDOMIDE GRINDEKS CAPSULE, HARD 7.5MG	1147/22T	1147/22T	AS GRINDEKS	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LENALIDOMIDE GRINDEKS CAPSULE, HARD 25MG	1151/22T	1151/22T	AS GRINDEKS	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LENALIDOMIDE GRINDEKS CAPSULE, HARD 15MG	1149/22T	1149/22T	AS GRINDEKS	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LENALIDOMIDE GRINDEKS CAPSULE, HARD 20MG	1150/22T	1150/22T	AS GRINDEKS	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally

				Authorised Products
LENALIDOMIDE GRINDEKS CAPSULE, HARD 10MG	1148/22T	1148/22T	AS GRINDEKS	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
LENALIDOMIDE GRINDEKS CAPSULE, HARD 2.5MG	7244/21T	7244/21T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 5MG	7245/21T	7245/21T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 7.5MG	7246/21T	7246/21T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 25MG	7250/21T	7250/21T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of

				Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 15MG	7248/21T	7248/21T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 20MG	7249/21T	7249/21T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of

				wording agreed by the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 10MG	7247/21T	7247/21T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	5669/21T	5669/21T	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
EFEXOR XR PROLONGED RELEASE CAPSULES 37.5MG	5670/21T	5670/21T	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
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	5668/21T	5668/21T	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
HOLESTATIN TABLET, FILM COATED 10MG	5457/22T, 5458/22T	5457/22T, 5458/22T	DEMO 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
HOLESTATIN TABLET, FILM COATED 40MG	5453/22T, 5454/22T	5453/22T, 5454/22T	DEMO 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
HOLESTATIN TABLET, FILM COATED 20MG	5455/22T, 5456/22T	5455/22T, 5456/22T	DEMO 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
HOLESTATIN TABLET, FILM COATED 5MG	5459/22T, 5460/22T	5459/22T, 5460/22T	DEMO 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
IBUTOMOL TABLET, FILM COATED 200MG/500MG	3765/22T	3765/22T	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)
BALANCE 4.25% GLUCOSE, 1.25MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	3664/22T, 3665/22T	3664/22T, 3665/22T	FRESENIUS MEDICAL CARE DEUTSCHLAND 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.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
BALANCE 1.5% GLUCOSE, 1.25MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	3666/22T, 3667/22T	3666/22T, 3667/22T	FRESENIUS MEDICAL CARE DEUTSCHLAND 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.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
BALANCE 2.3% GLUCOSE, 1.25MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	3662/22T, 3663/22T	3662/22T, 3663/22T	FRESENIUS MEDICAL CARE DEUTSCHLAND 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.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
BLISSEL VAGINAL GEL 50MCG/G	3377/22T	3377/22T	ITF HELLAS A.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) 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*
VOLTAREN D TABLET, DISPERSIBLE 50MG	539/22T	539/22T	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)
DEXAMED SOLUTION FOR INJECTION OR INFUSION 4MG/ML	3929/22T	3929/22T	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
DEXAMED SOLUTION FOR INJECTION OR INFUSION 4MG/ML	8579/21T, 8580/21T	8579/21T, 8580/21T	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.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
STREPSILS HONEY & LEMON LOZENGE	4497/22T	4497/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CODANOL TABLET	9511/22T	9511/22T	CRESCENT PHARMA INTERNATIONAL 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
IMODIUM PLUS TABLET 2MG/125MG	8896/21T	8896/21T	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
IMODIUM ORIGINAL CAPSULE, HARD 2MG	null	null	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

OLIMEL PERI N4E EMULSION FOR INFUSION	5439/22T, 5440/22T, 5441/22T, 5442/22T	5439/22T, 5440/22T, 5441/22T, 5442/22T	BAXTER (HELLAS) EPE	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)
OLIMEL N9E EMULSION FOR INFUSION	5431/22T, 5432/22T, 5433/22T, 5434/22T	5431/22T, 5432/22T, 5433/22T, 5434/22T	BAXTER (HELLAS) EPE	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)
OLIMEL N12E EMULSION FOR INFUSION	5427/22T, 5428/22T, 5429/22T, 5430/22T	5427/22T, 5428/22T, 5429/22T, 5430/22T	BAXTER (HELLAS) EPE	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)
OLIMEL N7E EMULSION FOR INFUSION	5435/22T, 5436/22T, 5437/22T, 5438/22T	5435/22T, 5436/22T, 5437/22T, 5438/22T	BAXTER (HELLAS) EPE	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)
ACCU-THYROX ORAL SOLUTION 100MCG/5ML	3280/22T	3280/22T	GALENICA 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)
ACCU-THYROX ORAL SOLUTION 25MCG/5ML	null	null	GALENICA 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)
ACCU-THYROX ORAL SOLUTION 50MCG/5ML	3279/22T	3279/22T	GALENICA 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)
SEPTOBORE EYE DROPS	849/20T	849/20T	COOPER PHARMACEUTICALS SA (COOPER S.A.)	C.I.1 a) The medicinal product is covered by the defined scope of the procedure
PLOTIS TABLET, FILM COATED 30MG	1736/22T	1736/22T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
PLOTIS TABLET, FILM COATED 60MG	1737/22T	1737/22T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
CITRAFLEET POWDER FOR ORAL SOLUTION	8724/21T	8724/21T	CASEN RECORDATI SL	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
MEMINI TABLET, FILM COATED 10MG	2660/21T	2660/21T	ELPEN PHARMACEUTICAL CO INC	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
MEMINI TABLET, FILM COATED 20MG	2661/21T	2661/21T	ELPEN PHARMACEUTICAL CO INC	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
ALLUZIENCE SOLUTION FOR INJECTION 200 SPEYWOOD UNITS/ML	5410/22T	5410/22T	IPSEN PHARMA	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
ZYLORIC TABLET 100MG	660/22T	660/22T	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
ZYLORIC TABLET 300MG	661/22T	661/22T	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
FERROUS GLUCONATE TABLET, COATED 300MG	2370/22T, 2371/22T, 2372/22T	2370/22T, 2371/22T, 2372/22T	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
FERROUS GLUCONATE TABLET, FILM COATED 300MG	2373/22T, 2374/22T, 2375/22T	2373/22T, 2374/22T, 2375/22T	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
IMIGRAN TABLET, FILM COATED 50MG	7177/20T	7177/20T	GLAXOSMITHKLINE (IRELAND) LIMITED	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
MAALOX PLUS ORAL SUSPENSION	3573/21T	3573/21T	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MAALOX PLUS ORAL SUSPENSION	3573/21T	3573/21T	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MAALOX PLUS TABLET, CHEWABLE	3574/21T	3574/21T	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MAALOX PLUS TABLET, CHEWABLE	3574/21T	3574/21T	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	3572/21T	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	3572/21T	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
STREPSILS COOL LOZENGE	4498/22T	4498/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
STREPSILS ORANGE WITH VITAMIN C LOZENGE	4496/22T	4496/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MIRENA INTRA UTERINE SYSTEM 52MG (20MCG/24h)	664/22T	664/22T	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
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G	9633/21T	9633/21T	FRESENIUS KABI 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
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	9632/21T	9632/21T	FRESENIUS KABI 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
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G	8681/21T	8681/21T	FRESENIUS KABI 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 C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	8679/21T	8679/21T	FRESENIUS KABI 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 C.I.2.a C.I.2.a -

				SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SPORAL CAPSULE, HARD 100MG	3612/22T	3612/22T	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
FRISIUM TABLET 10MG	57/20T	57/20T	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.
DEXETA EYE DROPS, SOLUTION 1.5MG/ML	8359/21T	8359/21T	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
BALANCE 1.5% GLUCOSE,1.75MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	3672/22T, 3673/22T	3672/22T, 3673/22T	FRESENIUS MEDICAL CARE DEUTSCHLAND 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.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
BALANCE 2.3% GLUCOSE, 1.75MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	3668/22T, 3669/22T	3668/22T, 3669/22T	FRESENIUS MEDICAL CARE DEUTSCHLAND 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.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
BALANCE 4.25% GLUCOSE, 1.75MMOL/L CALCIUM SOLUTION FOR PERITONEAL DIALYSIS	3670/22T, 3671/22T	3670/22T, 3671/22T	FRESENIUS MEDICAL CARE DEUTSCHLAND 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.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
DALMEVIN TABLET 50MG	2511/22T	2511/22T	MEDOCHEMIE LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
GEODON CAPSULE, HARD 20MG	3998/21T	3998/21T	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation 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
GEODON CAPSULE, HARD 80MG	4001/21T	4001/21T	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation 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
GEODON CAPSULE, HARD 40MG	3999/21T	3999/21T	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation 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
GEODON CAPSULE, HARD 60MG	4000/21T	4000/21T	UPJOHN HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation 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
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005MG/ML	4237/22T	4237/22T	INIBSA DENTAL S.L.U.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01MG/ML	4236/22T	4236/22T	INIBSA DENTAL S.L.U.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
FUCIDIN CREAM 2%	9397/21T, 9398/21T, 9399/21T, 9400/21T, 9401/21T, 9402/21T, 9403/21T, 9404/21T, 9405/21T	9397/21T, 9398/21T, 9399/21T, 9400/21T, 9401/21T, 9402/21T, 9403/21T, 9404/21T, 9405/21T	LEO PHARMA A/S	B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in sh B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition o 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.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, b B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -

				Change in the manufacturi B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi B.II.a.3.b.1 B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Chang B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change i
GLUCAGEN HYPOKIT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1MG	4936/21T, 3291/22T, 3292/22T, 3293/22T	4936/21T, 3291/22T, 3292/22T, 3293/22T	NOVO NORDISK 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 C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
TAVANIC PARENTERAL SOLUTION FOR INFUSION 500MG/100ML	1972/22T	1972/22T	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
TAVANIC TABLET, FILM COATED 500MG	1971/22T	1971/22T	SANOFI WINTHROP INDUSTRIE.	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
ALFUZOSIN AUROBINDO TABLET, PROLONGED-RELEASE 10MG	7543/21T	7543/21T	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)
ADRENALINE INJECTION 1MG/ML	3986/22T, 3987/22T, 3988/22T	3986/22T, 3987/22T, 3988/22T	NORIDEM ENTERPRISES LTD	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 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.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
LINEZOLID ACCORD TABLET, FILM COATED 600MG	4984/22T	4984/22T	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
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 40MG	1301/22T	1301/22T	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 20MG	1300/22T	1300/22T	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
RAFAZIL ORAL SOLUTION 1MG/1ML	8338/20T	8338/20T	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 require additional minor assessment, e.g. translations are not yet agreed upon
RAFAZIL ORAL SOLUTION 1MG/1ML	6983/21T	6983/21T	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
AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	8675/21T	8675/21T	IPSEN PHARMA	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
AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	2606/22T, 2607/22T, 2608/22T, 2609/22T, 2610/22T, 2611/22T	2606/22T, 2607/22T, 2608/22T, 2609/22T, 2610/22T, 2611/22T	IPSEN PHARMA	B.I.d.1.b.2 B.I.d.1.b.2 - 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 Su 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 manufacturi B.I.d.1.c B.I.d.1.c - 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 Suitab A.7 A.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
RAMIPRIL ACCORD CAPSULE, HARD 2.5MG	769/23T, 770/23T, 771/23T	769/23T, 770/23T, 771/23T	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
RAMIPRIL ACCORD CAPSULE, HARD 5MG	766/23T, 767/23T, 768/23T	766/23T, 767/23T, 768/23T	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
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/500MG	8778/22T, 8779/22T, 8780/22T	8778/22T, 8779/22T, 8780/22T	APC INSTYTUT SP. Z.O.O.	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.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.f B.II.b.5.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/1000MG	8775/22T, 8776/22T, 8777/22T	8775/22T, 8776/22T, 8777/22T	APC INSTYTUT SP. Z.O.O.	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.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.f B.II.b.5.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 100MG/1000MG	8772/22T, 8773/22T, 8774/22T	8772/22T, 8773/22T, 8774/22T	APC INSTYTUT SP. Z.O.O.	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.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.f B.II.b.5.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue
IONOLYTE SOLUTION FOR INFUSION	9870/22T	9870/22T	FRESENIUS KABI HELLAS A.E.	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
TACROLIMUS ACCORD OINTMENT 0.1%	560/23T	560/23T	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
BRUFEDOL TABLET, FILM COATED 600MG	2923/21T	2923/21T	VIATRIS HEALTHCARE 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)
BRUFEDOL TABLET, FILM COATED 400MG	2924/21T	2924/21T	VIATRIS HEALTHCARE 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)
BRUFEDOL TABLET, FILM COATED 200MG	2925/21T	2925/21T	VIATRIS HEALTHCARE 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)
VINORELBINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	448/23T	448/23T	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 JUBILANT TABLET, FILM COATED 5MG	8714/22T	8714/22T	JUBILANT PHARMACEUTICALS NV	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
DONEPEZIL JUBILANT TABLET, FILM COATED 5MG	8714/22T	8714/22T	JUBILANT PHARMACEUTICALS NV	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
DONEPEZIL JUBILANT TABLET, FILM COATED 10MG	8713/22T	8713/22T	JUBILANT PHARMACEUTICALS NV	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
DONEPEZIL JUBILANT TABLET, FILM COATED 10MG	8713/22T	8713/22T	JUBILANT PHARMACEUTICALS NV	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
AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	5233/22T, 5234/22T	5233/22T, 5234/22T	IPSEN PHARMA	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.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/immunol ogical product and any of the test methods performed at the site is a biological/immunol ogical method
DYSPORT POWDER FOR SOLUTION FOR INJECTION 500U	5235/22T, 5236/22T	5235/22T, 5236/22T	IPSEN M.E.P.E.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/impor ter 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 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/immunol ogical product and any of the test methods performed at the site is a biological/immunol ogical method
LAMIVUDINE/ZIDOVUDINE ACCORD TABLET, FILM COATED 150MG/300MG	4983/22T	4983/22T	ACCORD HEALTHCARE S.L.U	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
LAMIVUDINE/ZIDOVUDINE ACCORD TABLET, FILM COATED 150MG/300MG	4983/22T	4983/22T	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
FLUOROURACIL ACCORD SOLUTION FOR INJECTION OR INFUSION 50MG/ML	388/23T	388/23T	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)*
REVAMOX TABLET, FILM COATED 200MG	637/23T	637/23T	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)
AUGMENTIN TABLET, FILM COATED 1G	6573/22T	6573/22T	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
AUGMENTIN POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	6574/22T	6574/22T	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
AUGMENTIN TABLET, FILM COATED 500MG/125MG	6571/22T	6571/22T	GLAXOSMITHKLINE (IRELAND) LIMITED	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
AUGMENTIN ES POWDER FOR ORAL SUSPENSION (600+42.9)MG/5ML	6570/22T	6570/22T	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
AUGMENTIN MIXED FRUIT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	6572/22T	6572/22T	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
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.5% GLUCOSE, 1.75MMOL/L CALCIUM	973/23T, 974/23T	973/23T, 974/23T	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 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)
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 2.3% GLUCOSE, 1.75MMOL/L CALCIUM	969/23T, 970/23T	969/23T, 970/23T	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 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)
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 4.25% GLUCOSE, 1.75MMOL/L CALCIUM	971/23T, 972/23T	971/23T, 972/23T	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 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)
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 1.5% GLUCOSE	979/23T, 980/23T	979/23T, 980/23T	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 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)
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 2.3% GLUCOSE	977/23T, 978/23T	977/23T, 978/23T	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 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)
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 4.25% GLUCOSE	975/23T, 976/23T	975/23T, 976/23T	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 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)
ZITHROMAX POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	8678/20T	8678/20T	PFIZER HELLAS AE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
ZITHROMAX POWDER FOR ORAL SUSPENSION 200MG/5ML	8677/20T	8677/20T	PFIZER HELLAS AE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
CISPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	8676/20T	8676/20T	PFIZER HELLAS AE	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
LASIX SOLUTION FOR INJECTION 20MG/2ML	2583/23T	2583/23T	SANOFI WINTHROP INDUSTRIE.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ANDROXIL CUTANEOUS SOLUTION 5%	8309/22T	8309/22T	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
ANDROXIL CUTANEOUS SOLUTION 2%	8310/22T	8310/22T	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
DYSPORT POWDER FOR SOLUTION FOR INJECTION 500U	4402/21T	4402/21T	IPSEN M.E.P.E.	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
EFAVIRENZ AUROBINDO TABLET, FILM COATED 600MG	1/23T	1/23T	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
GYNO-CANESTEN VAGINAL CAPSULE, SOFT 500MG	8668/22T	8668/22T	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
FLUDEX FILM COATED, PROLONGED RELEASE TABLETS 1.5MG	7601/21T	7601/21T	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
ARVEKAP POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 11.25MG	2536/23T	2536/23T	IPSEN M.E.P.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
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 40MG	453/23T, 454/23T	453/23T, 454/23T	TAD 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
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 20MG	455/23T, 456/23T	455/23T, 456/23T	TAD 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
SELEX TABLET 5MG	1206/23T	1206/23T	CODAL SYNTO 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)*
PARACETAMOL/BAXTER SOLUTION FOR INFUSION 10MG/ML	447/23T	447/23T	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
HEXAFLU DAY & NIGHT TABLET 500MG/60MG AND 500MG/25MG	77/23T	77/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
ROPIVACAINE KABI SOLUTION FOR INJECTION 2MG/ML	9601/22T	9601/22T	FRESENIUS KABI HELLAS A.E.	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
ROPIVACAINE KABI SOLUTION FOR INFUSION 2MG/ML	9600/22T	9600/22T	FRESENIUS KABI HELLAS A.E.	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
ROPIVACAINE KABI SOLUTION FOR INJECTION 5MG/ML	9599/22T	9599/22T	FRESENIUS KABI HELLAS A.E.	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
ROPIVACAINE KABI SOLUTION FOR INJECTION 7.5MG/ML	9598/22T	9598/22T	FRESENIUS KABI HELLAS A.E.	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

ROPIVACAINE KABI SOLUTION FOR INJECTION 10MG/ML	9597/22T	9597/22T	FRESENIUS KABI HELLAS A.E.	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
STILNOX TABLET, FILM COATED 10MG	2596/23T, 2597/23T	2596/23T, 2597/23T	SANOFI WINTHROP INDUSTRIE.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.z A.z - ADMINISTRATIVE CHANGES - Other variation
LASIX SOLUTION FOR INJECTION 20MG/2ML	2634/23T	2634/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LASIX TABLET 40MG	2635/23T	2635/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CONCERTA TABLET, PROLONGED-RELEASE 36MG	9824/22T	9824/22T	JANSSEN-CILAG INTERNATIONAL NV	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or

				excipient (when mentioned in the dossier)*
CONCERTA TABLET, PROLONGED-RELEASE 18MG	9825/22T	9825/22T	JANSSEN-CILAG INTERNATIONAL NV	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CONCERTA TABLET, PROLONGED-RELEASE 54MG	9823/22T	9823/22T	JANSSEN-CILAG INTERNATIONAL NV	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DIOVAN ORAL SOLUTION 3MG/ML	9077/21T	9077/21T	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
LATAZ EYE DROPS, SOLUTION 50MCG/1ML(0.005% W/V)	9214/22T	9214/22T	RAFARM S.A.	C.I.z C.I.z - SAFETY,

				EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ISOPTO-MAXITROL EYE DROPS, SUSPENSION	1333/23T	1333/23T	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
FLUXIL CAPSULE, HARD 20MG	1335/23T	1335/23T	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
FEMOSTON TABLET, FILM COATED	2224/23T	2224/23T	VIATRIS HEALTHCARE LIMITED.	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
HOLESTATIN TABLET, FILM COATED 20MG	445/23T	445/23T	DEMO S.A.	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
PRIMPERAN TABLET 10MG	462/23T, 463/23T	462/23T, 463/23T	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
PRIMPERAN SOLUTION FOR INJECTION 10MG/2ML	464/23T, 465/23T	464/23T, 465/23T	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
STOVADIS TABLET, FILM COATED 25MG/5MG	9062/21T	9062/21T	LES LABORATOIRES SERVIER	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.
STOVADIS TABLET, FILM COATED 12.5MG/7.5MG	9061/21T	9061/21T	LES LABORATOIRES SERVIER	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.
STOVADIS TABLET, FILM COATED 25MG/7.5MG	9063/21T	9063/21T	LES LABORATOIRES SERVIER	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.
STOVADIS TABLET, FILM COATED 12.5MG/5MG	9060/21T	9060/21T	LES LABORATOIRES SERVIER	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.
STOVADIS TABLET, FILM COATED 6.25MG/7.5MG	9059/21T	9059/21T	LES LABORATOIRES SERVIER	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.
STOVADIS TABLET, FILM COATED 6.25MG/5MG	9058/21T	9058/21T	LES LABORATOIRES SERVIER	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.
CYTARABINE ACCORD SOLUTION FOR INJECTION OR INFUSION 100MG/ML	7052/22T, 7053/22T, 9547/22T, 9548/22T, 9549/22T	7052/22T, 7053/22T, 9547/22T, 9548/22T, 9549/22T	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
TADALAFIL ACCORD TABLET, FILM COATED 20MG	4986/22T	4986/22T	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 5MG	4987/22T	4987/22T	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
CUROSURF SUSPENSION FOR INJECTION 80MG/ML	654/22T	654/22T	CHIESI HELLAS A.E.B.E.	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*
MAXIDEX EYE DROPS, SUSPENSION 0.1% W/V	1271/23T	1271/23T	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
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	461/23T	461/23T	ACCORD HEALTHCARE S.L.U	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
LEVETIRACETAM NORIDEM CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	419/23T, 420/23T, 421/23T	419/23T, 420/23T, 421/23T	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.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
MUCOSOLVAN SOLUTION FOR INJECTION 7.5MG/ML, 2ML VIALS	318/23T	318/23T	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
ABIRATERONE/PHARMAZAC TABLET 250MG	2974/22T	2974/22T	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
ABIRATERONE/PHARMAZAC TABLET, FILM COATED 500MG	2975/22T	2975/22T	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
CANTEX TABLET, FILM COATED 200MG	9402/22T	9402/22T	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
CANTEX TABLET, FILM COATED 50MG	9403/22T	9403/22T	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
VOLTAREN INJECTION 75MG/3ML	2734/23T, 2735/23T	2734/23T, 2735/23T	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

VOLTAREN INJECTION 75MG/3ML	2734/23T, 2735/23T	2734/23T, 2735/23T	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
AZEPTIL CAPSULE, HARD 250MG	9394/22T, 9395/22T	9394/22T, 9395/22T	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 -
LIPITOR TABLET, FILM COATED 40MG	708/23T	708/23T	UPJOHN HELLAS 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
LIPITOR TABLET, FILM COATED 10MG	710/23T	710/23T	UPJOHN HELLAS 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
LIPITOR TABLET, FILM COATED 20MG	709/23T	709/23T	UPJOHN HELLAS 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
ZARATOR TABLET, FILM COATED 10MG	707/23T	707/23T	UPJOHN HELLAS 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
ZARATOR TABLET, FILM COATED 20MG	706/23T	706/23T	UPJOHN HELLAS 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
ZARATOR TABLET, FILM COATED 40MG	705/23T	705/23T	UPJOHN HELLAS 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
PULMOTON INHALATION POWDER, PRE-DISPENSED (100+6) MCG/DOSE	1077/23T	1077/23T	ELPEN PHARMACEUTICAL CO INC	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
PULMOTON INHALATION POWDER, PRE-DISPENSED (400+12) MCG/DOSE	1075/23T	1075/23T	ELPEN PHARMACEUTICAL CO INC	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
PULMOTON INHALATION POWDER, PRE-DISPENSED (200+6) MCG/DOSE	1076/23T	1076/23T	ELPEN PHARMACEUTICAL CO INC	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
DEFERASIROX PHARMASCIENCE TABLET, FILM COATED 90MG	9349/22T	9349/22T	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
DEFERASIROX PHARMASCIENCE TABLET, FILM COATED 360MG	9347/22T	9347/22T	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
DEFERASIROX PHARMASCIENCE TABLET, FILM COATED 180MG	9348/22T	9348/22T	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
SANDOSTATIN SOLUTION FOR INJECTION & INFUSION 0.1MG/ML	9350/22T	9350/22T	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)*
ULTRAVIST 370 SOLUTION FOR INJECTION 76.9%	2366/22T	2366/22T	BAYER HELLAS ABEE	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
ULTRAVIST 300 SOLUTION FOR INJECTION 62.34%	2367/22T	2367/22T	BAYER HELLAS ABEE	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
AMOXIL CAPSULE, HARD 500MG	9495/21T	9495/21T	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

				PRODUCTS - Other variation
TADALAFIL ACCORD TABLET, FILM COATED 20MG	9761/22T, 9762/22T	9761/22T, 9762/22T	ACCORD HEALTHCARE S.L.U	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TADALAFIL ACCORD TABLET, FILM COATED 5MG	9763/22T, 9764/22T	9763/22T, 9764/22T	ACCORD HEALTHCARE S.L.U	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a

				starting material, reagent or excipient (when mentioned in the dossier)*
SUTIREM CAPSULE, HARD 12.5MG	1068/23T	1068/23T	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)
SUTIREM CAPSULE, HARD 25MG	1067/23T	1067/23T	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)
SUTIREM CAPSULE, HARD 37.5MG	1066/23T	1066/23T	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)
SUTIREM CAPSULE, HARD 50MG	1065/23T	1065/23T	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)
OLARTAN TABLET, FILM COATED 10MG	64/23T, 65/23T, 66/23T	64/23T, 65/23T, 66/23T	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
OLARTAN-PLUS TABLET, FILM COATED 20MG/25MG	52/23T, 53/23T, 54/23T	52/23T, 53/23T, 54/23T	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
OLARTAN TABLET, FILM COATED 20MG	61/23T, 62/23T, 63/23T	61/23T, 62/23T, 63/23T	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
ORIZAL TABLET, FILM COATED 40MG/10MG	37/23T, 38/23T, 39/23T	37/23T, 38/23T, 39/23T	MENARINI INTERNATIONAL	C.I.11.a C.I.11.a - SAFETY,

			OPERATIONS LUXEMBOURG SA	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
ORIZAL TABLET, FILM COATED 20MG/5MG	43/23T, 44/23T, 45/23T	43/23T, 44/23T, 45/23T	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
ORIZAL TABLET, FILM COATED 40MG/5MG	40/23T, 41/23T, 42/23T	40/23T, 41/23T, 42/23T	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
OLARTAN-PLUS TABLET, FILM COATED 40MG/25MG	46/23T, 47/23T, 48/23T	46/23T, 47/23T, 48/23T	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
ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	25/23T, 26/23T, 27/23T	25/23T, 26/23T, 27/23T	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
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	34/23T, 35/23T, 36/23T	34/23T, 35/23T, 36/23T	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
ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	22/23T, 23/23T, 24/23T	22/23T, 23/23T, 24/23T	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
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	31/23T, 32/23T, 33/23T	31/23T, 32/23T, 33/23T	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
ORIZAL PLUS TABLET, FILM COATED 40/10/12.5MG	28/23T, 29/23T, 30/23T	28/23T, 29/23T, 30/23T	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
OLARTAN-PLUS TABLET, FILM COATED 40MG/12.5MG	49/23T, 50/23T, 51/23T	49/23T, 50/23T, 51/23T	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
OLARTAN-PLUS TABLET, FILM COATED 20MG/12.5MG	55/23T, 56/23T, 57/23T	55/23T, 56/23T, 57/23T	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
OLARTAN TABLET, FILM COATED 40MG	58/23T, 59/23T, 60/23T	58/23T, 59/23T, 60/23T	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
AMPICILLIN/SULBACTAM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/0.5G	9355/22T	9355/22T	APTA MEDICA INTERNACIONAL D.O.O.	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)
AMPICILLIN/SULBACTAM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G/1G	9354/22T	9354/22T	APTA MEDICA INTERNACIONAL D.O.O.	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)
MYOVIEW KIT FOR RADIOPHARMACEUTICAL PREPARATION 0.23MG	7732/20T	7732/20T	GE HEALTHCARE AS (NYDALEN)	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
DULCOLAX TABLET, GASTRO-RESISTANT 5MG	273/23T	273/23T	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)*
MUCOSOLVAN SOLUTION FOR INJECTION 7.5MG/ML, 2ML VIALS	274/23T	274/23T	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)*
LEVOXA TABLET, FILM COATED 500MG	262/23T	262/23T	TEVA BV	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
DICLAC 75 ID HEXAL TABLET, PROLONGED-RELEASE 75MG	11289/20T	11289/20T	HEXAL AG	B.II.b.3 a) Minor change in the manufacturing process
SPERSADEX COMP EYE DROPS	241/23T	241/23T	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
GEMCITABINE ACCORD POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	9162/22T	9162/22T	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

GEMCITABINE ACCORD POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	9161/22T	9161/22T	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
ZETIVASIM TABLET 10MG/80MG	745/23T	745/23T	ANFARM 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
ZETIVASIM TABLET 10MG/20MG	747/23T	747/23T	ANFARM 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
ZETIVASIM TABLET 10MG/40MG	746/23T	746/23T	ANFARM 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
ZETIVASIM TABLET 10MG/10MG	748/23T	748/23T	ANFARM 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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 60MG(6000IU)/0.6ML	1679/23T	1679/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG(2000IU)/0.2ML	1681/23T	1681/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG(4000IU)/0.4ML	1680/23T	1680/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 80MG(8000IU)/0.8ML	1678/23T	1678/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DIENOGEST BESINS TABLET 2MG	9589/22T, 9590/22T	9589/22T, 9590/22T	LABORATOIRES BESINS INTERNATIONAL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DIENOGEST BESINS TABLET 2MG	9589/22T, 9590/22T	9589/22T, 9590/22T	LABORATOIRES BESINS INTERNATIONAL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder B.III.1.a.2 B.III.1.a.2 -

				QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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/25MG	5561/22T	5561/22T	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/25MG	5564/22T	5564/22T	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/320MG/25MG	5560/22T	5560/22T	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/12.5MG	5563/22T	5563/22T	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	5562/22T	5562/22T	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
MOXILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	872/23T	872/23T	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
MOXILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	871/23T	871/23T	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
NOVANTRONE CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/ML	2/23T	2/23T	VIATRIS HEALTHCARE LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZYRTEC-D TABLET, PROLONGED-RELEASE 5MG/120MG	8599/22T	8599/22T	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
LOGNIF CAPSULE, HARD 0.5MG	296/23T, 297/23T	296/23T, 297/23T	TEVA 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
LENALIDOMIDE GRINDEKS CAPSULE, HARD 2.5MG	5122/21T	5122/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 2.5MG	5122/21T	5122/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 2.5MG	5122/21T	5122/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 5MG	5123/21T	5123/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 5MG	5123/21T	5123/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 5MG	5123/21T	5123/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 7.5MG	5117/21T	5117/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 7.5MG	5117/21T	5117/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 7.5MG	5117/21T	5117/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 25MG	5121/21T	5121/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 25MG	5121/21T	5121/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 25MG	5121/21T	5121/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 15MG	5119/21T	5119/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 15MG	5119/21T	5119/21T	AS GRINDEKS	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) C.I.z C.I.z -

				SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 15MG	5119/21T	5119/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 20MG	5120/21T	5120/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 20MG	5120/21T	5120/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 20MG	5120/21T	5120/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 10MG	5118/21T	5118/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 10MG	5118/21T	5118/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LENALIDOMIDE GRINDEKS CAPSULE, HARD 10MG	5118/21T	5118/21T	AS GRINDEKS	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) C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
PALEXIA RETARD TABLET, PROLONGED-RELEASE 200MG	8543/22T	8543/22T	GRUNENTHAL 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
PALEXIA RETARD TABLET, PROLONGED-RELEASE 250MG	8542/22T	8542/22T	GRUNENTHAL GMBH	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
PALEXIA RETARD TABLET, PROLONGED-RELEASE 50MG	8546/22T	8546/22T	GRUNENTHAL 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
PALEXIA TABLET, FILM COATED 50MG	8539/22T	8539/22T	GRUNENTHAL 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
PALEXIA TABLET, FILM COATED 75MG	8538/22T	8538/22T	GRUNENTHAL 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
PALEXIA ORAL SOLUTION 20MG/ML	8536/22T	8536/22T	GRUNENTHAL 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
PALEXIA RETARD TABLET, PROLONGED-RELEASE 25MG	8541/22T	8541/22T	GRUNENTHAL 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
PALEXIA ORAL SOLUTION 4MG/ML	8537/22T	8537/22T	GRUNENTHAL 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
PALEXIA RETARD TABLET, PROLONGED-RELEASE 150MG	8544/22T	8544/22T	GRUNENTHAL 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
PALEXIA TABLET, FILM COATED 100MG	8540/22T	8540/22T	GRUNENTHAL 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
PALEXIA RETARD TABLET, PROLONGED-RELEASE 100MG	8545/22T	8545/22T	GRUNENTHAL 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
LEVOFLOXACIN NORIDEM SOLUTION FOR INFUSION 5MG/ML	374/23T	374/23T	NORIDEM ENTERPRISES 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)
TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/10MG	5684/22T	5684/22T	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
TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/5MG	5685/22T	5685/22T	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
TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/5MG	5683/22T	5683/22T	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
TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/10MG	5686/22T	5686/22T	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
AREMED TABLET, FILM COATED 1MG	8453/22T	8453/22T	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
EXTRANEAL SOLUTION FOR PERITONEAL DIALYSIS	9633/22T	9633/22T	BAXTER (HELLAS) EPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PNEUMOVAX 23 SOLUTION FOR INJECTION IN PREFILLED SYRINGES 25MCG/0.5ML	8651/22T	8651/22T	MERCK SHARP & DOHME BV	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
LIPOPEN TABLET, FILM COATED 40MG/10MG	498/23T	498/23T	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 5MG/10MG	501/23T	501/23T	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	499/23T	499/23T	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	500/23T	500/23T	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
STAMARIL POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION IN PREFILLED SYRINGE	8222/22T	8222/22T	SANOFI PASTEUR.	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
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8221/22T	8221/22T	SANOFI PASTEUR.	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
FINGOLIMOD PHARMASCIENCE CAPSULE, HARD 0.5MG	9514/22T	9514/22T	PHARMASCIENCE INTERNATIONAL 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
OLIMEL PERI N4E EMULSION FOR INFUSION	7743/22T, 7744/22T, 7745/22T, 7746/22T, 7747/22T, 7748/22T, 7749/22T	7743/22T, 7744/22T, 7745/22T, 7746/22T, 7747/22T, 7748/22T, 7749/22T	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	7729/22T, 7730/22T, 7731/22T, 7732/22T, 7733/22T, 7734/22T, 7735/22T	7729/22T, 7730/22T, 7731/22T, 7732/22T, 7733/22T, 7734/22T, 7735/22T	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	7722/22T, 7723/22T,	7722/22T, 7723/22T,	BAXTER (HELLAS) EPE	B.I.b.1.c B.I.b.1.c - QUALITY

	7724/22T, 7725/22T, 7726/22T, 7727/22T, 7728/22T	7724/22T, 7725/22T, 7726/22T, 7727/22T, 7728/22T		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	7736/22T, 7737/22T, 7738/22T, 7739/22T, 7740/22T, 7741/22T, 7742/22T	7736/22T, 7737/22T, 7738/22T, 7739/22T, 7740/22T, 7741/22T, 7742/22T	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
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	5675/22T, 5676/22T, 5677/22T, 5678/22T, 5679/22T	5675/22T, 5676/22T, 5677/22T, 5678/22T, 5679/22T	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 manufacturi 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.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.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 manufacturi 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, starting material / intermediate /
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	5670/22T, 5671/22T, 5672/22T, 5673/22T, 5674/22T	5670/22T, 5671/22T, 5672/22T, 5673/22T, 5674/22T	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 manufacturi 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.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.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 manufacturi 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, starting material / intermediate /
MOXILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	1650/23T	1650/23T	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
MOXILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	1651/23T	1651/23T	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
CYTARABINE ACCORD SOLUTION FOR INJECTION OR INFUSION 100MG/ML	6153/22T	6153/22T	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)*
ERMYCIN TABLET, FILM COATED 250MG	1622/23T	1622/23T	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
ERMYCIN TABLET, FILM COATED 500MG	1621/23T	1621/23T	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
REVAMOX TABLET, FILM COATED 200MG	9866/22T	9866/22T	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
OCTORET SOLUTION FOR INJECTION OR INFUSION 40MG/ML	9078/22T	9078/22T	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
AVERNOL TABLET 6.25MG	6631/22T	6631/22T	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

AVERNOL TABLET 25MG	6630/22T	6630/22T	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
VIBRAMYCIN TABLET, DISPERSIBLE 100MG	9545/22T	9545/22T	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
DEXAMETHASONE/KABI SOLUTION FOR INJECTION 4MG/ML	6175/22T	6175/22T	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 - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LOSARTAN AUROBINDO TABLET, FILM COATED 50MG	9854/22T	9854/22T	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
ADVANTAN CREAM 0.1% (W/W)	82/23T, 83/23T, 84/23T, 85/23T, 86/23T, 87/23T	82/23T, 83/23T, 84/23T, 85/23T, 86/23T, 87/23T	LEO PHARMA A/S	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) 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
FERINJECT DISPERSION FOR INJECTION/INFUSION 50MG IRON/ML	46/22T	46/22T	VIFOR FRANCE	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.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
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 50MG/ML	1260/22T	1260/22T	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 asses C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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 TABLET, FILM COATED 10MG	9444/22T, 9445/22T, 9446/22T	9444/22T, 9445/22T, 9446/22T	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 TABLET, FILM COATED 20MG	9447/22T, 9448/22T, 9449/22T	9447/22T, 9448/22T, 9449/22T	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/25MG	9438/22T, 9439/22T, 9440/22T	9438/22T, 9439/22T, 9440/22T	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 TABLET, FILM COATED 40MG/10MG	9423/22T, 9424/22T, 9425/22T	9423/22T, 9424/22T, 9425/22T	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 TABLET, FILM COATED 20MG/5MG	9429/22T, 9430/22T, 9431/22T	9429/22T, 9430/22T, 9431/22T	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 TABLET, FILM COATED 40MG/5MG	9426/22T, 9427/22T, 9428/22T	9426/22T, 9427/22T, 9428/22T	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	9435/22T, 9436/22T, 9437/22T	9435/22T, 9436/22T, 9437/22T	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	9411/22T, 9412/22T, 9413/22T	9411/22T, 9412/22T, 9413/22T	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 20/5/12.5MG	9420/22T, 9421/22T, 9422/22T	9420/22T, 9421/22T, 9422/22T	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	9408/22T, 9409/22T, 9410/22T	9408/22T, 9409/22T, 9410/22T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG 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
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	9417/22T, 9418/22T, 9419/22T	9417/22T, 9418/22T, 9419/22T	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	9414/22T, 9415/22T, 9416/22T	9414/22T, 9415/22T, 9416/22T	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	9432/22T, 9433/22T, 9434/22T	9432/22T, 9433/22T, 9434/22T	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	9441/22T, 9442/22T, 9443/22T	9441/22T, 9442/22T, 9443/22T	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 TABLET, FILM COATED 40MG	9450/22T, 9451/22T, 9452/22T	9450/22T, 9451/22T, 9452/22T	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
SORIFEN LOZ LOZENGE 8.75MG	593/23T	593/23T	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
SERETIDE EVOHALER PRESSURISED INHALATION, SUSPENSION 25MCG/50MCG	9769/22T	9769/22T	GLAXOSMITHKLINE (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.
CATAFLAM TABLET, COATED 50MG	9038/22T	9038/22T	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
TOLTERODINE ACCORD TABLET, FILM COATED 2MG	9613/22T, 9614/22T	9613/22T, 9614/22T	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)*
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	7708/22T	7708/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	7706/22T	7706/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	7705/22T	7705/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	7707/22T	7707/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LIPOCOMB CAPSULE, HARD 10MG/10MG	4239/22T	4239/22T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	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
LIPOCOMB CAPSULE, HARD 20MG/10MG	4240/22T	4240/22T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	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
SALOFALK TABLET, GASTRO-RESISTANT 500MG	552/23T, 553/23T, 554/23T	552/23T, 553/23T, 554/23T	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NANOGAM SOLUTION FOR INFUSION 100MG/ML	9079/22T	9079/22T	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	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
LAMISIL TABLET 125MG	591/23T	591/23T	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
MAXIDEX EYE DROPS, SUSPENSION 0.1% W/V	2616/23T	2616/23T	NOVARTIS IRELAND LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	208/23T	208/23T	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
ALGOVIL SYRUP 100MG/5ML	8454/22T	8454/22T	IOULIA AND IRENE TSETI PHARMACEUTICAL LABORATORIES S.A.	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
TARWOXIN TABLET, FILM COATED 0.2MG	9822/22T	9822/22T	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
TARWOXIN TABLET, FILM COATED 0.3MG	9821/22T	9821/22T	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
TARWOXIN TABLET, FILM COATED 0.4MG	9820/22T	9820/22T	DELORBIS 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
ALBUMAN SOLUTION FOR INFUSION 40G/L	8895/22T	8895/22T	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	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
ALBUMAN SOLUTION FOR INFUSION 200G/L	8896/22T	8896/22T	PROTHYA BIOSOLUTIONS NETHERLANDS B.V.	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
APIXABAN/MYLAN TABLET, FILM COATED 2.5MG	7034/22T	7034/22T	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
APIXABAN/MYLAN TABLET, FILM COATED 5MG	7035/22T	7035/22T	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
IMIGRAN TABLET, FILM COATED 50MG	9864/22T, 9865/22T	9864/22T, 9865/22T	GLAXOSMITHKLINE (IRELAND) LIMITED	B.z B.z - QUALITY CHANGES - 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)*
BICALUTAMIDE ACCORD TABLET, FILM COATED 50MG	738/21T	738/21T	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)
IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	3675/22T	3675/22T	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)
IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	3674/22T	3674/22T	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)
IDARUBICIN ACCORD SOLUTION FOR INJECTION 10MG/10ML	3676/22T	3676/22T	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)
VIDEL TABLET 50MG	9718/22T	9718/22T	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
IKELAN TABLET, FILM COATED 100MG	8394/22T	8394/22T	MEDOCHEMIE LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
IKELAN TABLET, FILM COATED 25MG	8396/22T	8396/22T	MEDOCHEMIE LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
IKELAN TABLET, FILM COATED 50MG	8395/22T	8395/22T	MEDOCHEMIE LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation

CRESTOR TABLET, FILM COATED 40MG	9348/21T, 1759/22T, 1760/22T, 1761/22T	9348/21T, 1759/22T, 1760/22T, 1761/22T	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
CRESTOR TABLET, FILM COATED 40MG	9348/21T, 1759/22T, 1760/22T, 1761/22T	9348/21T, 1759/22T, 1760/22T, 1761/22T	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
CRESTOR TABLET, FILM COATED 20MG	9349/21T, 1762/22T, 1763/22T, 1764/22T	9349/21T, 1762/22T, 1763/22T, 1764/22T	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
CRESTOR TABLET, FILM COATED 20MG	9349/21T, 1762/22T, 1763/22T, 1764/22T	9349/21T, 1762/22T, 1763/22T, 1764/22T	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
CRESTOR TABLET, FILM COATED 10MG	9350/21T, 1765/22T, 1766/22T, 1767/22T	9350/21T, 1765/22T, 1766/22T, 1767/22T	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
CRESTOR TABLET, FILM COATED 10MG	9350/21T, 1765/22T, 1766/22T, 1767/22T	9350/21T, 1765/22T, 1766/22T, 1767/22T	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
CRESTOR TABLET, FILM COATED 5MG	9351/21T, 1768/22T, 1769/22T, 1770/22T	9351/21T, 1768/22T, 1769/22T, 1770/22T	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
CRESTOR TABLET, FILM COATED 5MG	9351/21T, 1768/22T, 1769/22T, 1770/22T	9351/21T, 1768/22T, 1769/22T, 1770/22T	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
SEIZAL TABLET 200MG	1673/23T	1673/23T	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 25MG	1676/23T	1676/23T	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
SEIZAL TABLET 100MG	1674/23T	1674/23T	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 50MG	1675/23T	1675/23T	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
BINOSTO EFFERVESCENT TABLET 70MG	9784/22T	9784/22T	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
NAROX TABLET, FILM COATED 30MG	590/23T	590/23T	DELORBIS PHARMACEUTICALS LTD	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 container that does not lead to the complete deletion of a strength or pharmaceutical form
NAROX TABLET, FILM COATED 60MG	589/23T	589/23T	DELORBIS PHARMACEUTICALS LTD	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 container that does not lead to the complete deletion of a strength or pharmaceutical form
NAROX TABLET, FILM COATED 90MG	588/23T	588/23T	DELORBIS PHARMACEUTICALS LTD	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 container that does not lead to the complete deletion of a strength or pharmaceutical form
NAROX TABLET, FILM COATED 120MG	587/23T	587/23T	DELORBIS PHARMACEUTICALS LTD	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 container that does not lead to the complete deletion of a strength or pharmaceutical form
ERMYCED POWDER FOR ORAL SUSPENSION 250MG/5ML	1623/23T	1623/23T	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
ERMYCED POWDER FOR ORAL SUSPENSION 125MG/5ML	1624/23T	1624/23T	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
MOXILEN POWDER FOR ORAL SUSPENSION 125MG/5ML	1642/23T	1642/23T	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
MOXILEN FORTE POWDER FOR ORAL SUSPENSION 250MG/5ML	1641/23T	1641/23T	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
RITHROCLAD TABLET, FILM COATED 250MG	1932/23T	1932/23T	CODAL-SYNTO 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
RITHROCLAD TABLET, FILM COATED 500MG	1931/23T	1931/23T	CODAL-SYNTO 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
LECALCIF ORAL DROPS SOLUTION 2400IU/ML	799/23T	799/23T	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
OXYCONTIN TABLET, PROLONGED-RELEASE 80MG	619/23T	619/23T	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 5MG	623/23T	623/23T	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	622/23T	622/23T	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	621/23T	621/23T	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	620/23T	620/23T	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
PLATOREL TABLET, FILM COATED 10MG	9604/22T	9604/22T	ELPEN PHARMACEUTICAL CO INC	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)
PLATOREL TABLET, FILM COATED 40MG	9602/22T	9602/22T	ELPEN PHARMACEUTICAL CO INC	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)

PLATOREL TABLET, FILM COATED 20MG	9603/22T	9603/22T	ELPEN PHARMACEUTICAL CO INC	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)
PLATOREL TABLET, FILM COATED 5MG	9605/22T	9605/22T	ELPEN PHARMACEUTICAL CO INC	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)
UNIDROPS EYE DROPS, SOLUTION 20MG/ML	625/22T	625/22T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	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 - Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of medicinal products
STREPSILS LEMON SUGAR FREE LOZENGE	4499/22T	4499/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
AGGRASTAT CONCENTRATE FOR SOLUTION FOR INFUSION 0.25MG/ML	1599/23T	1599/23T	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)
OXYCONTIN TABLET, PROLONGED-RELEASE 5MG	1664/23T	1664/23T	MUNDIPHARMA 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
OXYCONTIN TABLET, PROLONGED-RELEASE 80MG	1656/23T	1656/23T	MUNDIPHARMA 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
OXYNORM CAPSULE, HARD 10MG	1666/23T	1666/23T	MUNDIPHARMA 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
OXYNORM CAPSULE, HARD 5MG	1667/23T	1667/23T	MUNDIPHARMA 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
OXYNORM SOLUTION FOR INJECTION OR INFUSION 10MG/ML	1661/23T	1661/23T	MUNDIPHARMA 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

OXYNORM LIQUID ORAL SOLUTION 5MG/5ML	1660/23T	1660/23T	MUNDIPHARMA 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
OXYNORM CAPSULE, HARD 20MG	1665/23T	1665/23T	MUNDIPHARMA 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
OXYCONTIN TABLET, PROLONGED-RELEASE 20MG	1663/23T	1663/23T	MUNDIPHARMA 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
OXYNORM SOLUTION FOR INJECTION OR INFUSION 50MG/ML	1662/23T	1662/23T	MUNDIPHARMA 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
OXYCONTIN TABLET, PROLONGED-RELEASE 10MG	1658/23T	1658/23T	MUNDIPHARMA 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
OXYCONTIN TABLET, PROLONGED-RELEASE 40MG	1657/23T	1657/23T	MUNDIPHARMA 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
OXYNORM CONCENTRATE ORAL SOLUTION 10MG/ML	1659/23T	1659/23T	MUNDIPHARMA 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
ARVEKAP POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 3.75MG	2535/23T	2535/23T	IPSEN M.E.P.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
SPECENIB TABLET, FILM COATED 50MG	598/23T	598/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SPECENIB TABLET, FILM COATED 100MG	595/23T	595/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SPECENIB TABLET, FILM COATED 140MG	594/23T	594/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SPECENIB TABLET, FILM COATED 20MG	599/23T	599/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SPECENIB TABLET, FILM COATED 80MG	596/23T	596/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SPECENIB TABLET, FILM COATED 70MG	597/23T	597/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TAVANIC TABLET, FILM COATED 500MG	1677/23T	1677/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AMANT TABLET 3MG	2329/23T	2329/23T	CODAL-SYNTO LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TIRABICIN TABLET, FILM COATED 150MG	2585/23T	2585/23T	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/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)
MIDAZOLAM ACCORD SOLUTION FOR INJECTION OR INFUSION 1MG/ML	8064/22T	8064/22T	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)*
MIDAZOLAM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	8065/22T	8065/22T	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)*
TOBRADEX EYE DROPS, SUSPENSION 0,1% w/v + 0,3% w/v	2311/23T	2311/23T	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
TOBRADEX EYE OINTMENT	2310/23T	2310/23T	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
LENALIDOMIDE GRINDEKS CAPSULE, HARD 2.5MG	513/22T	513/22T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by

				the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 5MG	514/22T	514/22T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 7.5MG	515/22T	515/22T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

LENALIDOMIDE GRINDEKS CAPSULE, HARD 25MG	519/22T	519/22T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 15MG	517/22T	517/22T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 20MG	518/22T	518/22T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY,

				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
LENALIDOMIDE GRINDEKS CAPSULE, HARD 10MG	516/22T	516/22T	AS GRINDEKS	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
NU-SEALS TABLET, GASTRO-RESISTANT 75MG	1368/23T	1368/23T	PHADISCO LTD	A.5.a A.5.a The activities for which the manufacturer/importer is responsible

				include batch release
VOLTAREN OPHTHA EYE DROPS 0.1%	2225/23T, 2226/23T, 2227/23T	2225/23T, 2226/23T, 2227/23T	LABORATOIRES THEA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CARDILOR TABLET 200MG	1324/23T	1324/23T	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
SELEGOS TABLET 5MG	1390/23T	1390/23T	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)*
TOBRADEX EYE DROPS, SUSPENSION 0,1% w/v + 0,3% w/v	2377/23T	2377/23T	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
TOBRADEX EYE OINTMENT	2376/23T	2376/23T	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

TRIATEC TABLET 2.5MG	1620/23T	1620/23T	SANOFI-AVENTIS GROUPE	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TRIATEC TABLET 5MG	1619/23T	1619/23T	SANOFI-AVENTIS GROUPE	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LATAZ-CO EYE DROPS, SOLUTION (50MCG+5MG)/ML	9389/22T	9389/22T	RAFARM S.A.	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
AXETINE POWDER FOR SOLUTION FOR INJECTION/INFUSION 250MG/VIAL	4693/22T	4693/22T	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 POWDER FOR SOLUTION FOR INJECTION/INFUSION 1.5G	4691/22T	4691/22T	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 POWDER FOR SOLUTION FOR INJECTION/INFUSION 750MG/VIAL	4692/22T	4692/22T	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
NEXIUM I.V. POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG	2114/23T	2114/23T	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)*
VIDELMET TABLET, FILM COATED 50MG/850MG	543/23T	543/23T	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/int

				ermediate 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
VIDELMET TABLET, FILM COATED 50MG/1000MG	542/23T	542/23T	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
FOUCH VAGINAL CREAM 2%	1367/23T	1367/23T	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

TRIACOR TABLET, PROLONGED-RELEASE 5MG/5MG	2467/23T, 2468/23T	2467/23T, 2468/23T	SANOFI WINTHROP INDUSTRIE.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.z A.z - ADMINISTRATIVE CHANGES - Other variation
TOPISTIN SOLUTION FOR INTRAVENOUS INFUSION 2MG/ML	2136/23T, 2137/23T, 2138/23T	2136/23T, 2137/23T, 2138/23T	ELPEN PHARMACEUTICAL CO INC	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 an C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following

				assessment of the same change for the reference product - Implementation of change(s) 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
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 20MG/ML	8897/22T	8897/22T	TEVA 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
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	8898/22T	8898/22T	TEVA 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
MODIODAL TABLET 100MG	8899/22T	8899/22T	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
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 200MCG	1780/23T, 1781/23T	1780/23T, 1781/23T	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
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 200MCG	1780/23T, 1781/23T	1780/23T, 1781/23T	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
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 200MCG	1780/23T, 1781/23T	1780/23T, 1781/23T	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
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 400MCG	1778/23T, 1779/23T	1778/23T, 1779/23T	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

MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 400MCG	1778/23T, 1779/23T	1778/23T, 1779/23T	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
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 400MCG	1778/23T, 1779/23T	1778/23T, 1779/23T	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
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8492/22T	8492/22T	GLAXOSMITHKLINE BIOLOGICALS 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
WELLBUTRIN XR MODIFIED-RELEASE TABLET 150MG	7087/21T	7087/21T	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*
WELLBUTRIN XR MODIFIED-RELEASE TABLET 300MG	7088/21T	7088/21T	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*
ACTILYSE POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1MG/ML	6760/22T, 6761/22T, 6762/22T, 6763/22T, 6764/22T, 6765/22T	6760/22T, 6761/22T, 6762/22T, 6763/22T, 6764/22T, 6765/22T	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation 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

CAPOLEV PLUS TABLET 16/12.5MG	1097/23T	1097/23T	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
CAPOLEV PLUS TABLET 8/12.5MG	1098/23T	1098/23T	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
CAPOLEV PLUS TABLET 32/25MG	1095/23T	1095/23T	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
CAPOLEV PLUS TABLET 32/12.5MG	1096/23T	1096/23T	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
NOVANTRONE CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/ML	9550/21T, 9551/21T	9550/21T, 9551/21T	VIATRIS HEALTHCARE LIMITED.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MEDOQUIP TABLET, FILM COATED 0.5MG	269/23T, 270/23T	269/23T, 270/23T	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
MEDOQUIP TABLET, FILM COATED 2MG	265/23T, 266/23T	265/23T, 266/23T	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
MEDOQUIP TABLET, FILM COATED 5MG	263/23T, 264/23T	263/23T, 264/23T	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
MEDOQUIP TABLET, FILM COATED 0.25MG	271/23T, 272/23T	271/23T, 272/23T	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
MEDOQUIP TABLET, FILM COATED 1MG	267/23T, 268/23T	267/23T, 268/23T	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
ROVASYN TABLET, FILM COATED 5MG	409/23T, 410/23T, 411/23T, 412/23T, 413/23T	409/23T, 410/23T, 411/23T, 412/23T, 413/23T	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
ROVASYN TABLET, FILM COATED 40MG	394/23T, 395/23T, 396/23T, 397/23T, 398/23T	394/23T, 395/23T, 396/23T, 397/23T, 398/23T	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
ROVASYN TABLET, FILM COATED 20MG	399/23T, 400/23T, 401/23T, 402/23T, 403/23T	399/23T, 400/23T, 401/23T, 402/23T, 403/23T	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
ROVASYN TABLET, FILM COATED 10MG	404/23T, 405/23T, 406/23T, 407/23T, 408/23T	404/23T, 405/23T, 406/23T, 407/23T, 408/23T	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

DONEPEZIL ACCORD TABLET, FILM COATED 5MG	9269/22T	9269/22T	ACCORD HEALTHCARE S.L.U	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
DONEPEZIL ACCORD TABLET, FILM COATED 10MG	9268/22T	9268/22T	ACCORD HEALTHCARE S.L.U	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
CRESTOR TABLET, FILM COATED 40MG	1346/22T	1346/22T	ASTRAZENECA AB	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
CRESTOR TABLET, FILM COATED 20MG	1345/22T	1345/22T	ASTRAZENECA AB	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
CRESTOR TABLET, FILM COATED 10MG	1344/22T	1344/22T	ASTRAZENECA AB	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
CRESTOR TABLET, FILM COATED 5MG	1343/22T	1343/22T	ASTRAZENECA AB	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
NEXIUM TABLET, GASTRO-RESISTANT 40MG	2115/23T	2115/23T	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)*
NEXIUM TABLET, GASTRO-RESISTANT 20MG	2116/23T	2116/23T	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)*
LYBEREN TABLET, FILM COATED 1000MG	9198/22T	9198/22T	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
LYBEREN TABLET, FILM COATED 250MG	9201/22T	9201/22T	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
LYBEREN TABLET, FILM COATED 500MG	9200/22T	9200/22T	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
LYBEREN TABLET, FILM COATED 750MG	9199/22T	9199/22T	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
ASPIREM TABLET, GASTRO-RESISTANT 75MG	1109/23T	1109/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BETAISODONA DRY POWDER, CUTANEOUS SPRAY 2.5% W/W	536/23T	536/23T	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
LIPOPEN TABLET, FILM COATED 40MG/10MG	9616/22T	9616/22T	ELPEN PHARMACEUTICAL CO INC	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 5MG/10MG	9619/22T	9619/22T	ELPEN PHARMACEUTICAL CO INC	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 20MG/10MG	9617/22T	9617/22T	ELPEN PHARMACEUTICAL CO INC	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	9618/22T	9618/22T	ELPEN PHARMACEUTICAL CO INC	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)
NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	492/23T, 493/23T, 494/23T, 495/23T, 496/23T, 497/23T	492/23T, 493/23T, 494/23T, 495/23T, 496/23T, 497/23T	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	486/23T, 487/23T, 488/23T, 489/23T, 490/23T, 491/23T	486/23T, 487/23T, 488/23T, 489/23T, 490/23T, 491/23T	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
IMUPRIN TABLET, FILM COATED 50MG	509/23T	509/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ZETIVASIM TABLET 10MG/20MG	469/23T	469/23T	ANFARM HELLAS 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
NETIN CAPSULE, HARD 300MG	459/23T	459/23T	DELORBIS PHARMACEUTICALS LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
NETIN CAPSULE, HARD 100MG	460/23T	460/23T	DELORBIS PHARMACEUTICALS LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
NETIN CAPSULE, HARD 400MG	458/23T	458/23T	DELORBIS PHARMACEUTICALS LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
TRIATEC PLUS TABLET 5MG/25MG	1348/23T	1348/23T	SANOFI-AVENTIS GROUPE	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
TAVANIC PARENTERAL SOLUTION FOR INFUSION 500MG/100ML	9357/22T	9357/22T	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	9358/22T	9358/22T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
STOVADIS TABLET, FILM COATED 25MG/5MG	7030/22T	7030/22T	LES LABORATOIRES SERVIER	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)
STOVADIS TABLET, FILM COATED 12.5MG/7.5MG	7029/22T	7029/22T	LES LABORATOIRES SERVIER	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)
STOVADIS TABLET, FILM COATED 25MG/7.5MG	7031/22T	7031/22T	LES LABORATOIRES SERVIER	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)
STOVADIS TABLET, FILM COATED 12.5MG/5MG	7028/22T	7028/22T	LES LABORATOIRES SERVIER	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)
STOVADIS TABLET, FILM COATED 6.25MG/7.5MG	7027/22T	7027/22T	LES LABORATOIRES SERVIER	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)
STOVADIS TABLET, FILM COATED 6.25MG/5MG	7026/22T	7026/22T	LES LABORATOIRES SERVIER	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)
SOLIFENACIN SANDOZ TABLET, FILM COATED 5MG	9637/22T	9637/22T	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
SOLIFENACIN SANDOZ TABLET, FILM COATED 10MG	9636/22T	9636/22T	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
CINNARON CAPSULE, HARD 75MG	275/23T, 276/23T, 277/23T, 278/23T, 279/23T, 280/23T, 281/23T, 282/23T, 283/23T, 284/23T, 285/23T, 286/23T, 287/23T, 288/23T, 289/23T	275/23T, 276/23T, 277/23T, 278/23T, 279/23T, 280/23T, 281/23T, 282/23T, 283/23T, 284/23T, 285/23T, 286/23T, 287/23T, 288/23T, 289/23T	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 correspo 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 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.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
YASMINELLE TABLET, FILM COATED 0.02MG/3MG	8760/22T	8760/22T	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
YASMIN TABLET, FILM COATED 0.03MG/3MG	8761/22T	8761/22T	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
METRONIDAZOLE TABLET 200MG	356/23T	356/23T	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
METRONIDAZOLE TABLET 250MG	355/23T	355/23T	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
SPIRO TABLET 100MG	1275/23T, 1276/23T	1275/23T, 1276/23T	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
SPIRO TABLET 25MG	1277/23T, 1278/23T	1277/23T, 1278/23T	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

TEGRETOL TABLET 200MG	9549/21T	9549/21T	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
TEGRETOL CR MODIFIED-RELEASE TABLET 400MG	9547/21T	9547/21T	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
TEGRETOL SYRUP 100MG/5ML	9546/21T	9546/21T	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
TEGRETOL CR MODIFIED-RELEASE TABLET 200MG	9548/21T	9548/21T	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
LETROZOLE TEVA TABLET, FILM COATED 2.5MG	9737/22T	9737/22T	TEVA PHARMA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GLITISOL TABLET 5MG	1915/23T, 1916/23T, 1917/23T, 1918/23T	1915/23T, 1916/23T, 1917/23T, 1918/23T	REMEDICA LTD	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.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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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
TOBREX EYE DROPS 0.3% W/V	948/23T	948/23T	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
DIVAMENSTRAL CAPSULE, HARD 226MG	9851/22T, 9852/22T, 9853/22T	9851/22T, 9852/22T, 9853/22T	MEDIS GMBH	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 fla 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.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
SANDIMMUN NEORAL CAPSULE, SOFT 100MG	9840/22T	9840/22T	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
SANDIMMUN NEORAL CAPSULE, SOFT 25MG	9842/22T	9842/22T	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
SANDIMMUN NEORAL CAPSULE, SOFT 50MG	9841/22T	9841/22T	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
SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML	9839/22T	9839/22T	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
MAVIXAN TABLET, ORODISPERSIBLE 5MG	444/23T	444/23T	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
MAVIXAN TABLET, ORODISPERSIBLE 10MG	443/23T	443/23T	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
LOGNIF CAPSULE, HARD 0.5MG	424/23T, 425/23T	424/23T, 425/23T	TEVA GMBH	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.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
MUNDISAL GEL ORAL GEL 8.71% W/W	7786/22T	7786/22T	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
AUDAX EAR DROPS 20% W/V	7787/22T	7787/22T	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
LATAZ EYE DROPS, SOLUTION 50MCG/1ML(0.005% W/V)	9184/22T	9184/22T	RAFARM S.A.	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
OLOXICAM SOLUTION FOR INJECTION 10MG/ML	9327/22T	9327/22T	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
ZETIVASIM TABLET 10MG/40MG	468/23T	468/23T	ANFARM HELLAS 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
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 180MG	9457/22T, 9458/22T, 9459/22T	9457/22T, 9458/22T, 9459/22T	ACCORD HEALTHCARE S.L.U	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.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
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 360MG	9454/22T, 9455/22T, 9456/22T	9454/22T, 9455/22T, 9456/22T	ACCORD HEALTHCARE S.L.U	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.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
OLOXICAM TABLET 15MG	1325/23T	1325/23T	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)*
GAVISCON PEPPERMINT TABLET, CHEWABLE	9404/22T	9404/22T	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
VOLTAREN FOR CHILDREN SUPPOSITORY 12.5MG	8733/22T	8733/22T	NOVARTIS IRELAND LIMITED	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
EZIPOL GASTRO-RESISTANT CAPSULE, HARD 20MG	8740/22T	8740/22T	KLEVA PHARMACEUTICALS S.A. (TRADING AS KLEVA S.A.)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Other variation
IMODIUM PLUS TABLET 2MG/125MG	9273/22T	9273/22T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
LOVAREM TABLET 20MG	3155/23T	3155/23T	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
NIDAGYL CAPSULE, HARD 500MG	218/23T	218/23T	DELORBIS PHARMACEUTICALS 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 that require additional minor assessment, e.g. translations are not yet agreed upon.

MABRON SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	219/23T	219/23T	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
OPTODROP-CO EYE DROPS, SOLUTION (2+0.5)%	914/23T	914/23T	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
TRIPAN TABLET, FILM COATED 20MG	1110/23T	1110/23T	DELORBIS PHARMACEUTICALS 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
TRIPAN TABLET, FILM COATED 5MG	1111/23T	1111/23T	DELORBIS PHARMACEUTICALS 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
OZEP TABLET 400MG	1083/23T	1083/23T	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
OZEP TABLET 600MG	1082/23T	1082/23T	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
OZEP TABLET 200MG	1084/23T	1084/23T	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
OZEP TABLET 800MG	1081/23T	1081/23T	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
OPTODROP EYE DROPS, SOLUTION 2% W/V	913/23T	913/23T	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
FELEXIN POWDER FOR ORAL SUSPENSION 125MG/5ML	1809/23T	1809/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
FELEXIN POWDER FOR ORAL SUSPENSION 250MG/5ML	1808/23T	1808/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

ARLEVERT TABLET	169/23T, 170/23T	169/23T, 170/23T	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
LATAZ-CO EYE DROPS, SOLUTION (50MCG+5MG)/ML	9487/22T	9487/22T	RAFARM S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
KLERIMED TABLET, FILM COATED 500MG	2052/23T	2052/23T	MEDOCHEMIE LTD	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
FRUTENOR SOLUTION FOR INJECTION OR INFUSION 1G/5ML	216/23T	216/23T	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
VENLAXIN TABLET, PROLONGED-RELEASE 225MG	739/23T	739/23T	IASIS PHARMACEUTICALS HELLAS 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)
VENLAXIN TABLET, PROLONGED-RELEASE 150MG	740/23T	740/23T	IASIS PHARMACEUTICALS HELLAS 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)
VENLAXIN TABLET, PROLONGED-RELEASE 75MG	741/23T	741/23T	IASIS PHARMACEUTICALS HELLAS 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)
ERLOTINIB REMEDICA TABLET, FILM COATED 25MG	8254/22T, 8255/22T, 8256/22T, 8257/22T, 8258/22T, 8259/22T, 8260/22T, 8261/22T	8254/22T, 8255/22T, 8256/22T, 8257/22T, 8258/22T, 8259/22T, 8260/22T, 8261/22T	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 substan 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.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.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.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 substanc
ERLOTINIB REMEDICA TABLET, FILM COATED 150MG	8238/22T, 8239/22T, 8240/22T, 8241/22T, 8242/22T, 8243/22T, 8244/22T, 8245/22T	8238/22T, 8239/22T, 8240/22T, 8241/22T, 8242/22T, 8243/22T, 8244/22T, 8245/22T	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 substan 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.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.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.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 substanc
ERLOTINIB REMEDICA TABLET, FILM COATED 50MG	8262/22T, 8263/22T, 8264/22T, 8265/22T, 8266/22T, 8267/22T, 8268/22T, 8269/22T	8262/22T, 8263/22T, 8264/22T, 8265/22T, 8266/22T, 8267/22T, 8268/22T, 8269/22T	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 substan 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.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.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.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 substanc
ERLOTINIB REMEDICA TABLET, FILM COATED 100MG	8246/22T, 8247/22T, 8248/22T, 8249/22T, 8250/22T, 8251/22T, 8252/22T, 8253/22T	8246/22T, 8247/22T, 8248/22T, 8249/22T, 8250/22T, 8251/22T, 8252/22T, 8253/22T	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 substan 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.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.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.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 substanc
ISOREM TABLET, SUBLINGUAL 5MG	1775/23T	1775/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ISOREM TABLET 10MG	1774/23T	1774/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
OXCARBAZEPINE JUBILANT TABLET, FILM COATED 300MG	5030/22T	5030/22T	JUBILANT PHARMACEUTICALS NV	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.
OXCARBAZEPINE JUBILANT TABLET, FILM COATED 600MG	5029/22T	5029/22T	JUBILANT PHARMACEUTICALS NV	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.
TARWOXIN TABLET, FILM COATED 0.2MG	124/23T	124/23T	DELORBIS PHARMACEUTICALS 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.
TARWOXIN TABLET, FILM COATED 0.3MG	123/23T	123/23T	DELORBIS PHARMACEUTICALS 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.
TARWOXIN TABLET, FILM COATED 0.4MG	122/23T	122/23T	DELORBIS PHARMACEUTICALS 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.
VIRUCID TABLET 200MG	9212/22T	9212/22T	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

VIRUCID TABLET 400MG	9211/22T	9211/22T	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
VIRUCID TABLET 800MG	9210/22T	9210/22T	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
PANTOFLUX TABLET, GASTRO-RESISTANT 40MG	6874/22T	6874/22T	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
PANTOFLUX TABLET, GASTRO-RESISTANT 20MG	6875/22T	6875/22T	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
DUMOZOL TABLET, FILM COATED 250MG	212/23T	212/23T	TEVA BV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DUMOZOL TABLET, FILM COATED 500MG	211/23T	211/23T	TEVA BV	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

				VETERINARY MEDICINAL PRODUCTS - Other variation
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/25MG	2918/22T	2918/22T	VIATRIS 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
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/12.5MG	2916/22T	2916/22T	VIATRIS 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
OLMEDIPIN PLUS TABLET, FILM COATED 20MG/5MG/12.5MG	2919/22T	2919/22T	VIATRIS 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
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/12.5MG	2915/22T	2915/22T	VIATRIS 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
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/25MG	2917/22T	2917/22T	VIATRIS 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
SALMETEROL + FLUTICASONE/MYLAN PRESSURISED INHALATION, SUSPENSION 25MCG/250MCG	7911/22T	7911/22T	VIATRIS LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation

TUTECVI TABLET 50MG	7910/22T	7910/22T	VIATRIS LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/25MG	7913/22T	7913/22T	VIATRIS LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/12.5MG	7915/22T	7915/22T	VIATRIS LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/25MG	7914/22T	7914/22T	VIATRIS LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/5MG/12.5MG	7916/22T	7916/22T	VIATRIS LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
OLMEDIPIN PLUS TABLET, FILM COATED 20MG/5MG/12.5MG	7917/22T	7917/22T	VIATRIS LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
SALMETEROL + FLUTICASONE/MYLAN PRESSURISED INHALATION, SUSPENSION 25MCG/125MCG	7912/22T	7912/22T	VIATRIS LIMITED	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
DELIPOST TABLET, FILM COATED 10MG	907/23T	907/23T	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
DELIPOST TABLET, FILM COATED 20MG	906/23T	906/23T	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
DELIPOST TABLET, FILM COATED 40MG	905/23T	905/23T	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
PULMICORT NEBULISER SUSPENSION 0.25MG/ML	100/23T	100/23T	ASTRAZENECA AB	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
PULMICORT NEBULISER SUSPENSION 0.5MG/ML	99/23T	99/23T	ASTRAZENECA AB	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
CARVIDEX TABLET 25MG	9228/22T	9228/22T	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
CARVIDEX 12.5 TABLET 12.5MG	9225/22T	9225/22T	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
CARVIDEX TABLET 6.25MG	9226/22T	9226/22T	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
CARVIDEX 3.125 TABLET 3.125MG	9227/22T	9227/22T	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
AUGMENTIN ES POWDER FOR ORAL SUSPENSION (600+42.9)MG/5ML	6847/22T	6847/22T	GLAXOSMITHKLINE (IRELAND) 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.
VOLTAREN D TABLET, DISPERSIBLE 50MG	207/23T	207/23T	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
VALTREX TABLET, FILM COATED 500MG	98/23T	98/23T	GLAXOSMITHKLINE (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 ENEMA 4G/60ML	652/23T, 653/23T	652/23T, 653/23T	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
SALOFALK SUPPOSITORY 500MG	654/23T, 655/23T	654/23T, 655/23T	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
MOXARIN POWDER FOR INJECTION 1G/VIAL	2087/23T	2087/23T	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
MOXARIN POWDER FOR INJECTION 500MG/VIAL	2088/23T	2088/23T	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
ROCUDEM SOLUTION FOR INJECTION OR INFUSION 10MG/ML	631/23T, 632/23T	631/23T, 632/23T	NORIDEM ENTERPRISES 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 B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

BUTOLIR NEBULISER SUSPENSION 0.5MG/2ML	9346/22T	9346/22T	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
BUTOLIR NEBULISER SUSPENSION 1MG/2ML	9345/22T	9345/22T	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
AXETINE TABLET, FILM COATED 250MG	1910/23T	1910/23T	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
AXETINE TABLET, FILM COATED 500MG	1909/23T	1909/23T	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
OXYNORM CAPSULE, HARD 10MG	951/23T	951/23T	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)
OXYNORM CAPSULE, HARD 5MG	952/23T	952/23T	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)
OXYNORM CAPSULE, HARD 20MG	950/23T	950/23T	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)
AMARYL TABLET 2MG	1220/23T	1220/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AMARYL TABLET 3MG	1219/23T	1219/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AMARYL TABLET 4MG	1218/23T	1218/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
AMARYL TABLET 1MG	1221/23T	1221/23T	SANOFI WINTHROP INDUSTRIE.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MEDOVENT TABLET 30MG	5/23T	5/23T	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
NETIN CAPSULE, HARD 300MG	2731/23T	2731/23T	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	2732/23T	2732/23T	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 400MG	2730/23T	2730/23T	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
ATARAX SYRUP 2MG/ML	926/23T	926/23T	UCB PHARMA SA	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
TOBREX EYE OINTMENT 0.3% W/W	883/23T	883/23T	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
RINGER LACTATE/BAXTER(VIAFLO) SOLUTION FOR INFUSION	4/23T	4/23T	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
TERGIO TABLET, FILM COATED 14MG	870/23T	870/23T	TAW PHARMA (IRELAND) 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
PAROXETINE AUROBINDO TABLET, FILM COATED 30MG	624/23T	624/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
PAROXETINE AUROBINDO TABLET, FILM COATED 20MG	625/23T	625/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
DIOVAN TABLET, FILM COATED 160MG	8741/22T	8741/22T	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
DIOVAN TABLET, FILM COATED 40MG	8743/22T	8743/22T	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
DIOVAN TABLET, FILM COATED 80MG	8742/22T	8742/22T	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
OLOXICAM TABLET 15MG	9326/22T	9326/22T	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
GEODON CAPSULE, HARD 20MG	225/23T	225/23T	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)*
GEODON CAPSULE, HARD 40MG	224/23T	224/23T	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)*
GEODON CAPSULE, HARD 60MG	223/23T	223/23T	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)*
GEODON CAPSULE, HARD 80MG	222/23T	222/23T	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)*
IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	7240/22T, 762/23T, 763/23T	7240/22T, 762/23T, 763/23T	ACCORD HEALTHCARE S.L.U	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 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
IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	7239/22T, 760/23T, 761/23T	7239/22T, 760/23T, 761/23T	ACCORD HEALTHCARE S.L.U	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. 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 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
IDARUBICIN ACCORD SOLUTION FOR INJECTION 10MG/10ML	7241/22T, 764/23T, 765/23T	7241/22T, 764/23T, 765/23T	ACCORD HEALTHCARE S.L.U	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 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
LEVETIRACETAM NORIDEM CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	7770/22T	7770/22T	NORIDEM ENTERPRISES 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)
INFLUVAC SUB-UNIT TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	8511/22T	8511/22T	VIATRIS HEALTHCARE LIMITED.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
LIPOCOMB CAPSULE, HARD 10MG/10MG	9299/22T	9299/22T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	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
LIPOCOMB CAPSULE, HARD 20MG/10MG	9298/22T	9298/22T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	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
BISOLOC TABLET, FILM COATED 5MG	1907/23T	1907/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
BISOLOC TABLET, FILM COATED 10MG	1906/23T	1906/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
BISOLOC TABLET, FILM COATED 2.5MG	1908/23T	1908/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
NEISVAC-C SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 10MCG/0.5ML	72/23T, 73/23T	72/23T, 73/23T	PFIZER HELLAS AE	B.I.z B.I.z - Quality change - Active substance - Other variation 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
ESMOBETA SOLUTION FOR INJECTION 10MG/ML	550/23T, 551/23T	550/23T, 551/23T	NORIDEM ENTERPRISES 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
ESMOBETA SOLUTION FOR INFUSION 10MG/ML	548/23T, 549/23T	548/23T, 549/23T	NORIDEM ENTERPRISES 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
PHOXILIUM SOLUTION FOR HAEMOFILTRATION, HAEMODIAFILTRATION AND HAEMODIALYSIS	6493/22T, 6494/22T, 6495/22T, 6496/22T, 6497/22T, 6498/22T, 6499/22T, 6500/22T, 6501/22T, 6502/22T	6493/22T, 6494/22T, 6495/22T, 6496/22T, 6497/22T, 6498/22T, 6499/22T, 6500/22T, 6501/22T, 6502/22T	BAXTER HOLDING 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 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.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.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.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
PROGRAF CAPSULE, HARD 5MG	8654/22T	8654/22T	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 CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	8652/22T	8652/22T	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	8653/22T	8653/22T	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	8655/22T	8655/22T	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CRESTOR TABLET, FILM COATED 40MG	7418/22T, 7419/22T, 7420/22T, 7421/22T, 7422/22T	7418/22T, 7419/22T, 7420/22T, 7421/22T, 7422/22T	ASTRAZENECA AB	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.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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.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.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/impor

				ter of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible
CRESTOR TABLET, FILM COATED 20MG	7423/22T, 7424/22T, 7425/22T, 7426/22T, 7427/22T	7423/22T, 7424/22T, 7425/22T, 7426/22T, 7427/22T	ASTRAZENECA AB	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.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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.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.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/impor

				ter of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible
CRESTOR TABLET, FILM COATED 10MG	7428/22T, 7429/22T, 7430/22T, 7431/22T, 7432/22T	7428/22T, 7429/22T, 7430/22T, 7431/22T, 7432/22T	ASTRAZENECA AB	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.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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.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.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/impor

				ter of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible
CRESTOR TABLET, FILM COATED 5MG	7413/22T, 7414/22T, 7415/22T, 7416/22T, 7417/22T	7413/22T, 7414/22T, 7415/22T, 7416/22T, 7417/22T	ASTRAZENECA AB	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.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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.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.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/impor

				ter of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible
DONEPEZIL ACCORD TABLET, FILM COATED 5MG	8722/22T	8722/22T	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
DONEPEZIL ACCORD TABLET, FILM COATED 10MG	8721/22T	8721/22T	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
ZIPION TABLET 45MG	9386/22T	9386/22T	ZENTIVA K.S.	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
ZIPION TABLET 30MG	9387/22T	9387/22T	ZENTIVA K.S.	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
ZIPION TABLET 15MG	9388/22T	9388/22T	ZENTIVA K.S.	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
SODIUM CHLORIDE/BAXTER(VIAFLO) SOLUTION FOR INFUSION 0.9% W/V	9837/22T	9837/22T	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
PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	9836/22T	9836/22T	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
LOTEMAX EYE DROPS 0.5%	8798/22T	8798/22T	DR.GERHARD MANN CHEM.-PHARM. FABRIK GMBH	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
RAFAZIL ORAL SOLUTION 1MG/1ML	9662/21T	9662/21T	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
FINGOLIMOD SAPIENS CAPSULE, HARD 0.5MG	1844/23T	1844/23T	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
MOXICLAV TABLET, FILM COATED 1G	1653/23T	1653/23T	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
MOXICLAV TABLET, FILM COATED 625MG	1654/23T	1654/23T	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
MOXICLAV TABLET, FILM COATED 375MG	1655/23T	1655/23T	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
URSOFALK ORAL SUSPENSION 250MG/5ML	749/23T	749/23T	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
GABANTIN CAPSULE, HARD 300MG	806/23T, 807/23T	806/23T, 807/23T	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 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 asses
GABANTIN CAPSULE, HARD 400MG	804/23T, 805/23T	804/23T, 805/23T	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 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 asses
CLAREM TABLET, FILM COATED 500MG	9812/22T, 9813/22T, 9814/22T, 9815/22T	9812/22T, 9813/22T, 9814/22T, 9815/22T	REMEDICA LTD	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site

				where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CLAREM TABLET, FILM COATED 250MG	9816/22T, 9817/22T, 9818/22T, 9819/22T	9816/22T, 9817/22T, 9818/22T, 9819/22T	REMEDICA LTD	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
BOSENTAN ACCORD TABLET, FILM COATED 62.5MG	null	null	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
BOSENTAN ACCORD TABLET, FILM COATED 125MG	7492/22T	7492/22T	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
TOBI SOLUTION FOR INHALATION 300MG/5ML	9792/22T, 9793/22T, 9794/22T, 9795/22T	9792/22T, 9793/22T, 9794/22T, 9795/22T	VIATRIS HEALTHCARE 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 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.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
OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 20MG	7616/22T	7616/22T	JUBILANT PHARMACEUTICALS NV	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.
OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 10MG	7617/22T	7617/22T	JUBILANT PHARMACEUTICALS NV	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.
OLMESARTAN MEDOXOMIL JUBILANT TABLET, FILM COATED 40MG	7615/22T	7615/22T	JUBILANT PHARMACEUTICALS NV	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.
SORIL-MED ORANGE LOZENGE 2MG/0.60MG/1.20MG	7711/22T	7711/22T	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 C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SORIL-MED LEMON LOZENGE 3MG	7712/22T	7712/22T	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 C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
XYZAL TABLET, FILM COATED 5MG	134/23T	134/23T	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
XYZAL ORAL SOLUTION 0.5MG/ML	133/23T	133/23T	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
PREPARATION H RECTAL OINTMENT (1+3)%	2823/23T	2823/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	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
DICLAC 75 ID HEXAL TABLET, PROLONGED-RELEASE 75MG	9/23T	9/23T	HEXAL 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
REGAINE CUTANEOUS SOLUTION 5% W/V	8344/22T	8344/22T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
REGAINE CUTANEOUS SOLUTION 2% W/V	8345/22T	8345/22T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.a A.5.a The activities for which the manufacturer/importer is responsible

				include batch release
IMDUR TABLET, PROLONGED-RELEASE 60MG	7630/22T	7630/22T	TOPRIDGE PHARMA (IRELAND) 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
CRESTOR TABLET, FILM COATED 40MG	6831/22T, 6832/22T	6831/22T, 6832/22T	ASTRAZENECA AB	B.I.a.2.b B.I.a.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Substantial change to the manufacturing process of the active substance which may have a significant impact on the quality, safety or efficacy of the medicinal product 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
CRESTOR TABLET, FILM COATED 20MG	6833/22T, 6834/22T	6833/22T, 6834/22T	ASTRAZENECA AB	B.I.a.2.b B.I.a.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Substantial change to the manufacturing process of the active substance which may have a significant impact on the quality, safety or efficacy of the medicinal product 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
CRESTOR TABLET, FILM COATED 10MG	6835/22T, 6836/22T	6835/22T, 6836/22T	ASTRAZENECA AB	B.I.a.2.b B.I.a.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Substantial change to the manufacturing process of the active substance

				which may have a significant impact on the quality, safety or efficacy of the medicinal product 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
CRESTOR TABLET, FILM COATED 5MG	6829/22T, 6830/22T	6829/22T, 6830/22T	ASTRAZENECA AB	B.I.a.2.b B.I.a.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Substantial change to the manufacturing process of the active substance which may have a significant impact on the quality, safety or efficacy of the medicinal product 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
PARACETAMOL ACCORD TABLET 500MG	9774/22T	9774/22T	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)*
MOXILEN CAPSULE, HARD 500MG	728/23T	728/23T	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
MOXILEN CAPSULE, HARD 250MG	729/23T	729/23T	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
LOCERYL MEDICATED NAIL LACQUER 5% (W/V)	8943/22T	8943/22T	GALDERMA INTERNATIONAL ,FRANCE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BENYLIN MUCUS COUGH WARM HONEY & LEMON FLAVOUR SYRUP 20MG/ML	7825/22T, 7826/22T	7825/22T, 7826/22T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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.2.z B.IV.2.z - QUALITY CHANGES - Medical Devices - Change in specification parameters and/or limits of a measuring or administration device for veterinary medicinal products - Other variation
MOXARIN CAPSULE, HARD 500MG	2008/23T	2008/23T	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
MOXARIN CAPSULE, HARD 250MG	2009/23T	2009/23T	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
BENYLIN MUCUS COUGH WARM HONEY & LEMON FLAVOUR SYRUP 20MG/ML	8350/22T	8350/22T	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MICROLAX RECTAL SOLUTION (0.45G/0.0645G/4.465G)/DOSE	7242/22T	7242/22T	JOHNSON & JOHNSON	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES -

			HELLAS CONSUMER AE	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
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	8317/22T	8317/22T	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	8316/22T	8316/22T	NOVARTIS IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DYSPORT POWDER FOR SOLUTION FOR INJECTION 500U	869/23T	869/23T	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
RADICUT TABLET, FILM COATED 50MG/1000MG	9765/22T	9765/22T	GENEPHARM SA	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
RADICUT TABLET, FILM COATED 50MG/850MG	9766/22T	9766/22T	GENEPHARM SA	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
DEXAMED TABLET 1.5MG	4785/22T, 4786/22T, 4787/22T, 4788/22T	4785/22T, 4786/22T, 4787/22T, 4788/22T	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
DEXAMED TABLET 0.5MG	4789/22T, 4790/22T, 4791/22T, 4792/22T	4789/22T, 4790/22T, 4791/22T, 4792/22T	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
ATRONATE 'ONCE A WEEK' TABLET, FILM COATED 35MG	9867/22T	9867/22T	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
BUFAR EASYHALER POWDER FOR INHALATION 80MCG/4.5MCG/INHALATION	787/23T	787/23T	ORION CORPORATION (ORION PHARMA)	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)
INTRATECT SOLUTION FOR INFUSION 100G/L	8286/22T, 8287/22T	8286/22T, 8287/22T	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

INTRATECT SOLUTION FOR INFUSION 50G/L	8288/22T, 8289/22T	8288/22T, 8289/22T	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
ALMIRAL TABLET, GASTRO-RESISTANT 25MG	8329/22T, 8330/22T, 8331/22T	8329/22T, 8330/22T, 8331/22T	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)*
ALMIRAL TABLET, GASTRO-RESISTANT 50MG	8332/22T, 8333/22T, 8334/22T	8332/22T, 8333/22T, 8334/22T	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)*
TOBRADEX EYE DROPS, SUSPENSION 0,1% w/v + 0,3% w/v	9738/22T, 9739/22T	9738/22T, 9739/22T	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.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
TOBRADEX EYE DROPS, SUSPENSION 0,1% w/v + 0,3% w/v	9738/22T, 9739/22T	9738/22T, 9739/22T	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.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
VOLTAREN SUPPOSITORY 50MG	9043/22T	9043/22T	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	9042/22T	9042/22T	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	9048/22T	9048/22T	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	9044/22T	9044/22T	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	9049/22T	9049/22T	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	9047/22T	9047/22T	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	9045/22T	9045/22T	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	9046/22T	9046/22T	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
FERTILAN TABLET 50MG	862/23T	862/23T	CODAL-SYNTO LIMITED	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
ZEPILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 1G/VIAL	9701/22T	9701/22T	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
ZEPILEN POWDER FOR SOLUTION FOR INJECTION/INFUSION 500MG/VIAL	9702/22T	9702/22T	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
LEVETIRACETAM NORIDEM CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	7788/21T	7788/21T	NORIDEM ENTERPRISES 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
GAVISCON STRAWBERRY FLAVOUR TABLET, CHEWABLE	9717/22T	9717/22T	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
CLINIMIX N14G30E SOLUTION FOR INFUSION	9740/22T	9740/22T	BAXTER (HELLAS) EPE	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
MAGRILAN CAPSULE, HARD 20MG	735/23T	735/23T	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 POWDER FOR SOLUTION FOR INJECTION/INFUSION 1000MG/200MG	1652/23T	1652/23T	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
ADVANTAN EMULSION, CUTANEOUS 0.1% (W/W)	9719/22T, 9720/22T, 9721/22T, 9722/22T, 9723/22T, 9724/22T	9719/22T, 9720/22T, 9721/22T, 9722/22T, 9723/22T, 9724/22T	LEO PHARMA A/S	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.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
CISPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	7889/22T	7889/22T	PFIZER HELLAS AE	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
DICLODUO COMBI MODIFIED-RELEASE CAPSULE, HARD	9711/22T	9711/22T	PHARMASWISS CESKA REPUBLIKA SRO	B.II.a.2.b B.II.a.2.b - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change in the shape or dimensions of the pharmaceutical form - Gastro-resistant, modified or prolonged release pharmaceutical forms and scored tablets intended to be divided into equal doses
NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	540/23T, 541/23T	540/23T, 541/23T	BIAL-PORTELA & CA, 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)
NOPRILAM 250 POWDER FOR ORAL SUSPENSION (250MG/62.5MG)/5ML	538/23T, 539/23T	538/23T, 539/23T	BIAL-PORTELA & CA, 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)
DICLODUO COMBI MODIFIED-RELEASE CAPSULE, HARD	7230/22T	7230/22T	PHARMASWISS CESKA REPUBLIKA SRO	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
HALOXEN TABLET 5MG	1591/23T, 1592/23T, 1593/23T	1591/23T, 1592/23T, 1593/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGIL

				ANCE 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 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
HALOXEN TABLET 10MG	1594/23T, 1595/23T, 1596/23T	1594/23T, 1595/23T, 1596/23T	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 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
LIBRAX TABLET, COATED 5MG/2.5MG	1672/23T	1672/23T	VIATRIS HEALTHCARE 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)
SOLPADEINE SOLUBLE TABLET	9700/22T	9700/22T	OMEGA PHARMA HELLAS S.A	B.III.1 a) 1. New certificate from an already approved manufacturer
TRIATEC PLUS TABLET 5MG/25MG	9363/22T	9363/22T	SANOFI-AVENTIS GROUPE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AZACITIDINE PHARMASCIENCE POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	220/23T, 221/23T	220/23T, 221/23T	PHARMASCIENCE INTERNATIONAL 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 C.I.2.a C.I.2.a -

				SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MEDOVIR TABLET 800MG	9608/22T	9608/22T	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	9609/22T	9609/22T	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	9610/22T	9610/22T	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
COALIMAX TABLET 80/12.5MG	1605/23T	1605/23T	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
COALIMAX TABLET 80/25MG	1604/23T	1604/23T	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
COALIMAX TABLET 40/12.5MG	1606/23T	1606/23T	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
ZENAVIL TABLET, FILM COATED 5MG	6811/22T	6811/22T	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
ZENAVIL TABLET, FILM COATED 10MG	6810/22T	6810/22T	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
ZENAVIL TABLET, FILM COATED 20MG	6809/22T	6809/22T	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
VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	9668/22T, 9669/22T, 9670/22T	9668/22T, 9669/22T, 9670/22T	PFIZER HELLAS 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.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)
TRIOFAN FOR CHILDREN NASAL DROPS (0.5+5)MG	9557/22T	9557/22T	THE STAR MEDICINES IMPORTERS CO. LTD	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
TRIOFAN FOR ADULTS NASAL SPRAY (1+10)MG	9560/22T	9560/22T	THE STAR MEDICINES IMPORTERS CO. LTD	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
TRIOFAN FOR ADULTS NASAL DROPS (1+10)MG	9558/22T	9558/22T	THE STAR MEDICINES IMPORTERS CO. LTD	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
TRIOFAN FOR CHILDREN NASAL SPRAY (0.5+5)MG	9559/22T	9559/22T	THE STAR MEDICINES IMPORTERS CO. LTD	A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
SYNTOPINE TABLET 200MG	81/23T	81/23T	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)
PULMOCLASE <<SUGAR FREE>> SYRUP 750MG/5ML	858/23T	858/23T	GELENICA S.A.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation

DEXA-RHINASPRAY N NASAL SPRAY (0,02+0,12) MG/DOSE	9160/22T	9160/22T	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.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)
SPERSADEX COMP EYE DROPS	5878/22T, 5879/22T	5878/22T, 5879/22T	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) 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 -
LAMISIL TABLET 250MG	21/23T	21/23T	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
LAMISIL TABLET 250MG	21/23T	21/23T	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
MONOSORDIL MODIFIED-RELEASE CAPSULE, HARD 60MG	4654/22T	4654/22T	ELPEN PHARMACEUTICAL CO INC	B.I.z B.I.z - Quality change - Active substance - Other variation
NETENAX EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 3MG/ML	8762/22T	8762/22T	NEWLINE PHARMA, S.L.	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

NETENAX EYE DROPS, SOLUTION 3MG/ML	8763/22T	8763/22T	NEWLINE PHARMA, S.L.	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
CLARITYNE-D TABLET, PROLONGED-RELEASE 5MG/120MG	9698/22T	9698/22T	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
TEGRETOL TABLET 200MG	9562/22T	9562/22T	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
AMOXIL FORTE POWDER FOR ORAL SUSPENSION 250MG/5ML	9704/22T, 9705/22T, 9706/22T, 9707/22T, 9708/22T	9704/22T, 9705/22T, 9706/22T, 9707/22T, 9708/22T	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 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.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.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
FASTUM GEL 2.5%	7883/22T	7883/22T	A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE SRL	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DEMOLOX POWDER FOR SOLUTION FOR INJECTION/INFUSION 40MG/VIAL	782/23T	782/23T	NORIDEM ENTERPRISES 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
SODIUM CHLORIDE + GLUCOSE/BAXTER SOLUTION FOR INFUSION (0.9+5)% W/V	6/23T	6/23T	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
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01MG/ML	6790/22T, 6791/22T	6790/22T, 6791/22T	INIBSA DENTAL S.L.U.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template C.I.1.b C.I.1.b - 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 not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure and no new additional data is required to be submitted by the MAH
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005MG/ML	6788/22T, 6789/22T	6788/22T, 6789/22T	INIBSA DENTAL S.L.U.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template C.I.1.b C.I.1.b - 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 not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure and no new additional data is required to be submitted by the MAH
BETAISODONA OINTMENT 10% W/W	9556/22T	9556/22T	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
MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 1MG/ML	798/23T	798/23T	B. BRAUN MELSUNGEN AG	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
NETAXAN EYE DROPS, SOLUTION (3MG/1MG)/ML	8478/21T	8478/21T	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
NETAXAN EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (3MG/1MG)/ML	8477/21T	8477/21T	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
BETAISODONA VAGINAL DOUCHE 10% W/V	9185/22T, 9186/22T	9185/22T, 9186/22T	MUNDIPHARMA PHARMACEUTICALS LTD	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.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	9799/22T	9799/22T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	9797/22T	9797/22T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	9798/22T	9798/22T	MUNDIPHARMA PHARMACEUTICALS LTD	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	9796/22T	9796/22T	MUNDIPHARMA PHARMACEUTICALS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DELTIUS ORAL DROPS SOLUTION 10000IU/ML	7308/22T	7308/22T	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
DELTIUS ORAL SOLUTION 25000IU/2.5ML	7307/22T	7307/22T	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
CARDURA TABLET 2MG	9892/22T	9892/22T	UPJOHN HELLAS LTD	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
CARDURA TABLET 4MG	9891/22T	9891/22T	UPJOHN HELLAS LTD	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
MYOVIEW KIT FOR RADIOPHARMACEUTICAL PREPARATION 0.23MG	9887/22T	9887/22T	GE HEALTHCARE AS (NYDALEN)	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
IRINOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	7018/22T	7018/22T	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)*
WILATE 1000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	8640/22T	8640/22T	OCTAPHARMA (IP) SPRL	B.II.h.1.a B.II.h.1.a - QUALITY CHANGES - FINISHED PRODUCT - Adventitious Agents Safety - Update to the “Adventitious Agents Safety Evaluation” information (section 3.2.A.2) - Studies related to manufacturing steps investigated for the first time for one or more adventitious agents
WILATE 500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	8641/22T	8641/22T	OCTAPHARMA (IP) SPRL	B.II.h.1.a B.II.h.1.a - QUALITY CHANGES - FINISHED PRODUCT - Adventitious Agents Safety - Update to the “Adventitious Agents Safety Evaluation” information (section 3.2.A.2) - Studies related to manufacturing steps investigated for the first time for one or more adventitious agents
PROCTO-GLYVENOL RECTAL CREAM	9826/22T	9826/22T	RECORDATI HELLAS PHARMACEUTICALS 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
NAXAT TABLET, FILM COATED 15MG	9533/22T, 9534/22T, 9535/22T, 9536/22T	9533/22T, 9534/22T, 9535/22T, 9536/22T	DELORBIS PHARMACEUTICALS LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation 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.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 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)

NAXAT TABLET, FILM COATED 20MG	9529/22T, 9530/22T, 9531/22T, 9532/22T	9529/22T, 9530/22T, 9531/22T, 9532/22T	DELORBIS PHARMACEUTICALS LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation 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.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 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)
NAXAT TABLET, FILM COATED 10MG	9537/22T, 9538/22T, 9539/22T, 9540/22T	9537/22T, 9538/22T, 9539/22T, 9540/22T	DELORBIS PHARMACEUTICALS LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other

				variation 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.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 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)
RUFAN TABLET, FILM COATED 200MG	9606/22T	9606/22T	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
SKUDEXA TABLET, FILM COATED 75MG/25MG	9639/22T	9639/22T	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
SKUDEXA GRANULES FOR ORAL SOLUTION 75MG/25MG	9638/22T	9638/22T	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
MOXICLAV BIS POWDER FOR ORAL SUSPENSION 457MG/5ML	1647/23T	1647/23T	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
VENTOLIN DISKUS POWDER FOR INHALATION 200MCG	1643/23T	1643/23T	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)*
MOXICLAV POWDER FOR ORAL SUSPENSION 156.25MG/5ML	1646/23T	1646/23T	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
MOXICLAV FORTE POWDER FOR ORAL SUSPENSION 312,5MG/5ML	1645/23T	1645/23T	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
CREON 10000 CAPSULE, HARD 150MG	9640/22T	9640/22T	VIATRIS HEALTHCARE 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
SOLIFENACIN ACCORD TABLET, FILM COATED 5MG	9635/22T	9635/22T	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)*
SOLIFENACIN ACCORD TABLET, FILM COATED 10MG	9634/22T	9634/22T	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)*
MOXILEN CAPSULE, HARD 500MG	1617/23T	1617/23T	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
MOXILEN CAPSULE, HARD 250MG	1618/23T	1618/23T	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
DICLODUO COMBI MODIFIED-RELEASE CAPSULE, HARD	5990/22T	5990/22T	PHARMASWISS CESKA REPUBLIKA SRO	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
BETAISODONA VAGINAL GEL 10% W/W	9643/22T, 9644/22T	9643/22T, 9644/22T	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.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
CATAFLAM TABLET, COATED 50MG	555/23T	555/23T	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)
MONTELUKAST ACCORD TABLET, CHEWABLE 4MG	7516/22T	7516/22T	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)*
MONTELUKAST ACCORD TABLET, CHEWABLE 5MG	7515/22T	7515/22T	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)*
AMESOL TABLET, FILM COATED 500MG	9607/22T	9607/22T	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
OXYNORM CAPSULE, HARD 10MG	616/23T	616/23T	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 5MG	618/23T	618/23T	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	617/23T	617/23T	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
ABIRATERONE PHARMASCIENCE TABLET, FILM COATED 500MG	7618/22T	7618/22T	PHARMASCIENCE INTERNATIONAL 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
TEGRETOL CR MODIFIED-RELEASE TABLET 400MG	9563/22T	9563/22T	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
TEGRETOL CR MODIFIED-RELEASE TABLET 200MG	9564/22T	9564/22T	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
BRUFEDOL TABLET, FILM COATED 600MG	3102/21T	3102/21T	VIATRIS HEALTHCARE LIMITED.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
BRUFEDOL TABLET, FILM COATED 400MG	3103/21T	3103/21T	VIATRIS HEALTHCARE LIMITED.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products

BRUFEDOL TABLET, FILM COATED 200MG	3104/21T	3104/21T	VIATRIS HEALTHCARE LIMITED.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
BRUFEDOL TABLET, PROLONGED-RELEASE 800MG	3101/21T	3101/21T	VIATRIS HEALTHCARE LIMITED.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
EPLERENONE ACCORD TABLET, FILM COATED 25MG	6930/22T	6930/22T	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)
EPLERENONE ACCORD TABLET, FILM COATED 50MG	6929/22T	6929/22T	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)
OLMEDIPIN PLUS TABLET, FILM COATED 40MG/10MG/25MG	5687/22T	5687/22T	VIATRIS 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	5689/22T	5689/22T	VIATRIS 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	5690/22T	5690/22T	VIATRIS 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/25MG	5688/22T	5688/22T	VIATRIS 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	5691/22T	5691/22T	VIATRIS 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
FRUMIL TABLET	2147/23T, 2148/23T	2147/23T, 2148/23T	SANOFI WINTHROP INDUSTRIE.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - 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)*
BETAISODONA THROAT SPRAY OROMUCOSAL SPRAY 0.45% W/V	8348/22T, 8349/22T	8348/22T, 8349/22T	MUNDIPHARMA PHARMACEUTICALS LTD	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 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 OPHTHA EYE DROPS 0.1%	5880/22T, 5881/22T, 5882/22T, 5883/22T, 5884/22T, 5885/22T	5880/22T, 5881/22T, 5882/22T, 5883/22T, 5884/22T, 5885/22T	LABORATOIRES THEA	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.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
CURILEN CAPSULE, HARD 5MG/100MG	452/23T	452/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES 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
CURILEN CAPSULE, HARD 10MG/100MG	451/23T	451/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES 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
MOXARIN CAPSULE, HARD 250MG	860/23T	860/23T	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
MOXARIN CAPSULE, HARD 500MG	859/23T	859/23T	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

GABENIL CAPSULE, HARD 100MG	574/23T	574/23T	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
GABENIL CAPSULE, HARD 300MG	573/23T	573/23T	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
GABENIL CAPSULE, HARD 400MG	572/23T	572/23T	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
MONOSORDIL MODIFIED-RELEASE CAPSULE, HARD 60MG	7377/22T	7377/22T	ELPEN PHARMACEUTICAL CO INC	B.I.z B.I.z - Quality change - Active substance - Other variation
GLATIRAMER/MYLAN SOLUTION FOR INJECTION IN PREFILLED SYRINGES 40MG/ML	6876/22T	6876/22T	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
FUNGIFEX TABLET 250MG	9004/22T	9004/22T	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
EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	6671/22T	6671/22T	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
SIRANALEN ORAL SOLUTION 20MG/ML	7587/22T, 7588/22T	7587/22T, 7588/22T	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.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
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 500MG	7183/22T, 7184/22T	7183/22T, 7184/22T	MERCK A E HELLAS	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
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 750MG	7181/22T, 7182/22T	7181/22T, 7182/22T	MERCK A E HELLAS	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
GLUCOPHAGE SR TABLET, PROLONGED-RELEASE 1000MG	7179/22T, 7180/22T	7179/22T, 7180/22T	MERCK A E HELLAS	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
ADVANTAN EMULSION, CUTANEOUS 0.1% (W/W)	76/23T	76/23T	LEO PHARMA A/S	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
ADVANTAN CUTANEOUS SOLUTION 0.1% (W/V)	75/23T	75/23T	LEO PHARMA A/S	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
ADVANTAN CREAM 0.1% (W/W)	74/23T	74/23T	LEO PHARMA A/S	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
LEVOSERT INTRA UTERINE SYSTEM 52MG (20MCG/24h)	4028/22T	4028/22T	GEDEON RICHTER PLC	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
IMODIUM PLUS TABLET 2MG/125MG	8896/21T	8896/21T	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
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	8892/22T	8892/22T	SANOFI PASTEUR.	Change in the ELISA method for Bovine Serum Albumin content at the Inactivated Vero Trivalent Polio vaccine bulk stage
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	7520/22T, 7521/22T	7520/22T, 7521/22T	SANOFI PASTEUR.	B.I.b.2.d : Replacement of the method of determination of D-antigen content from sigmoid method to optimized parallel line method- Monovalent / Trivalent stages of IPV-containing vaccines.
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	9095/22T	9095/22T	SANOFI PASTEUR.	B.I.b.1.z) Change in the in-house specification of the diaminopimelic

				acid used as raw material in the manufacturing process of the Purified Diphtheria Toxoid active substance
TRILEPTAL TABLET, FILM COATED 600MG	6147/22T	6147/22T	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 - Register the alternate batch release site, Novartis Farmaceutica S.A., Barcelona, Spain for the finished product Trileptal 150 mg, 300 mg and 600 mg Film-coated tablets due to business reason
TRILEPTAL TABLET, FILM COATED 300MG	6148/22T	6148/22T	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 - Register the alternate batch release site, Novartis Farmaceutica S.A., Barcelona, Spain for the finished product Trileptal 150 mg, 300 mg and 600 mg Film-coated tablets due to business reason
TRILEPTAL TABLET, FILM COATED 150MG	6146/22T	6146/22T	NOVARTIS IRELAND LIMITED	B.II.b.2.c.1 - Register the alternate batch release site, Novartis Farmaceutica S.A., Barcelona, Spain for the finished product Trileptal 150 mg, 300 mg and 600 mg Film-coated tablets due to business reason
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	139/23T	139/23T	SANOFI PASTEUR.	B.I.c).1. b) Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological active substances
ENGERIX-B SUSPENSION FOR INJECTION 20MCG/1ML	1946/23T, 1947/23T	1946/23T, 1947/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.c.2.b -Deletion of the nitrogen content test from the Al(OH)3 release monograph
HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	1944/23T, 1945/23T	1944/23T, 1945/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.c.2.b -Deletion of the nitrogen content test from the Al(OH)3 release monograph
HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	1942/23T, 1943/23T	1942/23T, 1943/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.c.1.z-Alignment of the acceptance criterion of the ammonium limit

				test with Ph.Eur. Monograph 1664 (Aluminium hydroxide, hydrated, for adsorption), i.e. from `not more than 13 ppm' to `not more than 50 ppm')
ENGERIX-B PEDIATRIC SUSPENSION FOR INJECTION 10MCG/0.5ML	1948/23T, 1949/23T	1948/23T, 1949/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.c.1.z-Alignment of the acceptance criterion of the ammonium limit test with Ph.Eur. Monograph 1664 (Aluminium hydroxide, hydrated, for adsorption), i.e. from `not more than 13 ppm' to `not more than 50 ppm'
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	3582/22T	3582/22T	SANOFI PASTEUR.	B.I.b.1.z. This classification is aligned with what was proposed recently for the change in the in-house specifications of the pimelic acid used as raw material in the manufacturing process of the Purified Diphtheria Toxoid Drug Substance, submitted as WS EMEA/H/C/xxxx/WS/2262
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8893/22T	8893/22T	SANOFI PASTEUR.	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
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	7518/22T, 7519/22T	7518/22T, 7519/22T	SANOFI PASTEUR.	B.I.b).1. g) Widening of the approved specifications limits for starting materials/intermediates, which may have a significant effect on the overall quality of the active substance and/or the finished product 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
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	9096/22T	9096/22T	SANOFI PASTEUR.	B.I.b).1. z) Other variation
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	9096/22T	9096/22T	SANOFI PASTEUR.	B.I.b).1. z) Other variation
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	138/23T	138/23T	SANOFI PASTEUR.	B.I.c).1. b) Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological active substances B.II.b).3. b) Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product
PROGRAF CAPSULE, HARD 5MG	126/23T	126/23T	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.11. z) Other variation
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	125/23T	125/23T	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.11. z) Other variation
PROGRAF CAPSULE, HARD 1MG	127/23T	127/23T	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.11. z) Other variation
PROGRAF CAPSULE, HARD 0.5MG	128/23T	128/23T	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.11. z) Other variation
INFANRIX TETRA SUSPENSION FOR INJECTION	646/23T, 647/23T, 648/23T	646/23T, 647/23T, 648/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.a).3.z). Other variation B.II.b).3. z) Other variation B.II.d).2. z) [DEPRECATED] Other variation
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	649/23T, 650/23T, 651/23T	649/23T, 650/23T, 651/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.a).3.z). Other variation B.II.b).3. z) Other variation B.II.d).2. z) [DEPRECATED] Other variation
INFANRIX TETRA SUSPENSION FOR INJECTION	641/23T	641/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).2. z) [DEPRECATED] Other variation
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	640/23T	640/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).2. z) [DEPRECATED] Other variation

INFANRIX TETRA SUSPENSION FOR INJECTION	1938/23T, 1939/23T	1938/23T, 1939/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.c).1. z) Other variation B.II.c).2. b) Deletion of a test procedure if an alternative test procedure is already authorised
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	1940/23T, 1941/23T	1940/23T, 1941/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.c).1. z) Other variation B.II.c).2. b) Deletion of a test procedure if an alternative test procedure is already authorised
INFANRIX TETRA SUSPENSION FOR INJECTION	642/23T, 643/23T, 644/23T, 645/23T	642/23T, 643/23T, 644/23T, 645/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).4. z) Other variation B.I.b).1. z) Other variation B.I.b).2. z) [DEPRECATED] Other variation B.II.c).2. z) [DEPRECATED] Other variation
SUBUTEX TABLET, SUBLINGUAL 0.4MG	1456/23T	1456/23T	INDIVIOR EUROPE LIMITED	B.II.e).1.z). Other variation B.II.e).2. c) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
SUBUTEX TABLET, SUBLINGUAL 8MG	1455/23T	1455/23T	INDIVIOR EUROPE LIMITED	B.II.e).1.z). Other variation B.II.e).2. c) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
SUBUTEX TABLET, SUBLINGUAL 2MG	1454/23T	1454/23T	INDIVIOR EUROPE LIMITED	B.II.e).1.z). Other variation B.II.e).2. c) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	3581/22T	3581/22T	SANOFI PASTEUR.	B.I.b).1. z) Other variation
INFANRIX TETRA SUSPENSION FOR INJECTION	9727/22T	9727/22T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).2. z) [DEPRECATED] Other variation
INFANRIX TETRA SUSPENSION FOR INJECTION	9513/22T	9513/22T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).2. a) Minor change in the manufacturing process of the active substance

				procedure type IB
ZARATOR TABLET, FILM COATED 40MG	9488/22T, 9489/22T, 9490/22T	9488/22T, 9489/22T, 9490/22T	UPJOHN HELLAS LTD	B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site B.II.b).2.c). 1 Not including batch control/testing B.II.b.1.a: Addition of “Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary” as secondary packaging site. B.II.b.1.b: Addition of “Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary” as primary packaging site. B.II.b.2.c.1: Addition of “Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary” as batch release and importation site.
ZARATOR TABLET, FILM COATED 20MG	9491/22T, 9492/22T, 9493/22T	9491/22T, 9492/22T, 9493/22T	UPJOHN HELLAS LTD	B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site B.II.b).2.c). 1 Not including batch control/testing B.II.b.1.a: Addition of “Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary” as secondary packaging site. B.II.b.1.b: Addition of “Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary” as primary packaging site. B.II.b.2.c.1: Addition of “Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary” as batch release and importation site.
ZARATOR TABLET, FILM COATED 10MG	9494/22T, 9495/22T, 9496/22T	9494/22T, 9495/22T, 9496/22T	UPJOHN HELLAS LTD	B.II.b).1. a) Secondary packaging site B.II.b).1. b) Primary packaging site

				B.II.b).2.c). 1 Not including batch control/testing B.II.b.1.a: Addition of “Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary” as secondary packaging site. B.II.b.1.b: Addition of “Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary” as primary packaging site. B.II.b.2.c.1: Addition of “Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary” as batch release and importation site.
ACNATAC GEL	2585-2595/19T	2585-2595/19T	MEDA PHARMACEUTICALS S.A.	B.II.b.4.b Change in the batch size of the finished product - Downscaling down to 10-fold (Type IB by default) The current Canadian manufacturing site produces commercial batches of 2000 kg. The new alternative manufacturing site Madaus GmbH produces commercial batches of 1000 kg. B.II.d.2.a Minor changes to an approved test method for the finished product (Type IA) This variation concerns the HPLC Test method used for determination of clindamycin, methylparaben, propylparaben and clindamycin-related degradation products (STM04-125) The approved test

				method STM04-125 is amended with the following optional modifications: a) an alternative system suitability test b) extra wash-out phases to preserve the HPLC column c) using alternative calculation formulas Validation report from Madaus for the modified test method is provided in 3.2.P.5.3 B.II.d.2.a Minor changes to an approved test method for the finished product (Type IA) This variation concerns the HPLC method used for determination of tretinoin, butylhydroxytoluene and tretinoin-related degradation products (STM04-166) The approved test method STM04-166 is amended with the following optional modifications: a) an alternative system suitability test b) extra wash-out phases to preserve the HPLC main column. c) using a pre-column to preserve the main column d) alternative preparation of the sample solution (using methanol instead of THF and mobile phase) e) using alternative calculation formulas Validation report from Madaus for the modified test method is provided in 3.2.P.5.3 B.II.d.2.a Minor

				changes to an approved test method for the finished product (Type IA) This variation concerns the test method 2043-TM-319 used for determination of particle size. The currently approved test method is amended with the option of using equivalent equipment from another supplier. A validation report from Madaus using alternative equipment from another supplier is provided in 3.2.P.5.3. B.II.d.2.b Deletion of a test procedure if an alternative method is already authorised (Type IA) The historical test method E1097.01 for determination of particle size at an external laboratory is deleted. B.II.d.2.d Other changes to a test procedure (incl. replacement) for the finished product (Type IB) The historical viscosity test method SOP 02-39 is replaced with new method S0804_5.1. Due to different testing equipment at the testing sites two alternative test methods are proposed for determination of viscosity: In new method S0804_5.1 the viscosity of Acnatac gel is determined using "cone and plate" rotational

				viscometer equipment while in the already approved test method GM-V03 the viscosity of Acnatac gel is determined using a "spindle" rotational viscometer equipment. A validation report from Madaus for the new method S0804_5.1 is provided in 3.2.P.5.3. Column "Method" in 3.2.P.5.1 is updated accordingly. Editorial change in the context of the above test method changes: Test methods used for finished product testing are also used for testing of the bulk gel prior to filling into tubes. In module 3.2.P.3.4 the list of test methods is now replaced by a general note, saying that "Test methods used for bulk gel testing are identical to the test methods used for finished product testing (see 3.2.P.5.1)"
COVERSYL TABLET, FILM COATED 10MG	1847/19T	1847/19T	LES LABORATOIRES SERVIER	C.I. z) Other variation The Applicant proposes to update sections 4.8 with the addition of Raynaud's phenomenon. In line with the CMDh Recommandation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) No 1234/2008, this variation is classified as Type IAIN n°C.I.z. Additionally,

				following the End of Procedure of the worksharing FR/H/XXX/WS/78 (05/02/2018), the Applicant did not realize the addition of the below highlithed in yellow done by the RMS, in section 4 of the PIL. Therefore, it was agreed with the RMS to add it in the scope of the next variation with impact in the product information, as this present variation, as follows:
COVERSYL TABLET, FILM COATED 5MG	1846/19T	1846/19T	LES LABORATOIRES SERVIER	C.I. z) Other variation The Applicant proposes to update sections 4.8 with the addition of Raynaud's phenomenon. In line with the CMDh Recommandation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) No 1234/2008, this variation is classified as Type IAIN n°C.I.z. Additionally, following the End of Procedure of the worksharing FR/H/XXX/WS/78 (05/02/2018), the Applicant did not realize the addition of the below highlithed in yellow done by the RMS, in section 4 of the PIL. Therefore, it was agreed with the RMS to add it in the scope of the next variation with impact in the product information, as this present variation, as follows:
COVERSYL TABLET, FILM COATED 2.5MG	1845/19T	1845/19T	LES LABORATOIRES SERVIER	C.I. z) Other variation The Applicant

				proposes to update sections 4.8 with the addition of Raynaud's phenomenon. In line with the CMDh Recommandation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) No 1234/2008, this variation is classified as Type IAIN n°C.I.z. Additionally, following the End of Procedure of the worksharing FR/H/XXX/WS/78 (05/02/2018), the Applicant did not realize the addition of the below highlithed in yellow done by the RMS, in section 4 of the PIL. Therefore, it was agreed with the RMS to add it in the scope of the next variation with impact in the product information, as this present variation, as follows:
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	3766-3767/18T	3766-3767/18T	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.
ACNATAC GEL	2942/18T	2942/18T	MEDA PHARMACEUTICALS S.A.	C.I.1. a) The medicinal product is covered by the defined scope of the procedure C.I.1.a Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union referral procedure This Type IB variation is submitted to update the product information according to the outcome of referral procedure EMEA/H/A-31/1446 for retinoid-containing medicinal products. SmPC and PIL have been amended with the new text sections agreed in procedure EMEA/H/A-31/1446 for topically applied tretinoin. Some existing text sections have been deleted following the recommendations in section 2.4.2 Teratogenic effects - topical retinoids of the PRAC Assessment Report where it says "Where more extensive information already exists in the SmPC or package leaflet, it is considered that this should be retained unless it is more restrictive or contradicts the proposed wording by PRAC - in these cases that wording should be deleted. For clarification

				purposes, recommending the use of effective contraception to prevent pregnancy is considered more restrictive." In addition we would like to take the opportunity to amend the SmPC with the recent date of renewal and to notify minor editorial changes in the labeling text of outer and inner packaging. These changes in the labeling text have been proposed by the Icelandic authorities during renewal procedure SE/H/1134/01/R/01 . The common English version of Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labeling text is included in Module 1.3.1 - both tracked and clean.
COVERSYL TABLET, FILM COATED 10MG	2605-2607/18T	2605-2607/18T	LES LABORATOIRES SERVIER	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 IA.7 : to delete a drug product manufacturing site responsible for packaging : QUALITI (BURNLEY) LIMITED Talbot

				Street Briercliffe, Burnley Lancashire BB10 2JY - ENGLAND IAIN.B.II.b.1.a : in order to add the following secondary packaging sites : DERET LOGISTIQUE 580, rue du Champ Rouge 45770 SARAN FRANCE IAIN.B.II.b.1.a : in order to add the following secondary packaging sites : Limited Liability Company “Tamro” Noliktavu iela 5, Dreiliņi, Stopiņu novads, LV-2130, LATVIA

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