ΕΠΙΣΗΜΗ ΕΦΗΜΕΡΙΔΑ

ΤΗΣ ΚΥΠΡΙΑΚΗΣ ΔΗΜΟΚΡΑΤΙΑΣ

ΚΥΡΙΟ ΜΕΡΟΣ

ΤΜΗΜΑ Β

Αριθμός 5474	Παρασκευή, 9 Φεβρουαρίου 2024	527

Αριθμός 682

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: 168
   Ημερομηνία Έκδοσης Άδειας: 09/10/2023
   Ισχύει μέχρι: 08/10/2028
   Κάτοχος Άδειας: LUX PHARMA PARTICIPATIONS LTD
   Διεύθυνση Αλληλογραφίας: 57 Spyrou Kyprianou Avenue, BYBLOSERVE BUSINESS CENTRE, 2nd floor, 6051 Larnaca, Cyprus.

2. Αριθμός Άδειας: 169
   Ημερομηνία Έκδοσης Άδειας: 30/11/2023
   Ισχύει μέχρι: 29/11/2028
   Κάτοχος Άδειας: DAFECHEM LTD
   Διεύθυνση Αλληλογραφίας: 1, Ayias Lavras Street, Office 306, 2414 Nicosia, Cyprus.

Αριθμός 683

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: 022
   Ημερομηνία Έκδοσης Άδειας: 29/01/2004
   Προηγούμενη λήξη: 28/01/2024
   Ισχύει μέχρι: 28/01/2029
   Κάτοχος Άδειας: PANICOS THEO HADJIGEORGIOU & CO LTD
   Διεύθυνση Αλληλογραφίας: P.O.BOX 53158, 3301 LIMASSOL, Cyprus.

2. Αριθμός Άδειας: 097
   Ημερομηνία Έκδοσης Άδειας: 03/02/2014
   Προηγούμενη λήξη: 02/02/2024
   Ισχύει μέχρι: 02/02/2029
   Κάτοχος Άδειας: IOANNIS M. KAPAKIOTIS & SON LTD
   Διεύθυνση Αλληλογραφίας: P.O BOX 21464, 1509 NICOSIA, Cyprus.

3. Αριθμός Άδειας: 014
   Ημερομηνία Έκδοσης Άδειας: 13/10/2003
   Προηγούμενη λήξη: 12/10/2023
   Ισχύει μέχρι: 12/10/2028
   Κάτοχος Άδειας: ΒΑΡΝΑΒΑΣ ΧΑΤΖΗΠΑΝΑΓΗΣ ΛΤΔ
   Διεύθυνση Αλληλογραφίας: P.O.BOX 21005, 1500 Nicosia, Cyprus.

4. Αριθμός Άδειας: 140
   Ημερομηνία Έκδοσης Άδειας: 06/12/2018
   Προηγούμενη λήξη: 05/12/2023
   Ισχύει μέχρι: 05/12/2028
   Κάτοχος Άδειας: ACIC EUROPE LIMITED
   Διεύθυνση Αλληλογραφίας: 163, Leontiou Street, Clerimos Building, 2nd floor, 3022 Limassol, Cyprus.

5. Αριθμός Άδειας: 067
   Ημερομηνία Έκδοσης Άδειας: 29/04/2009
   Προηγούμενη λήξη: 28/04/2024
   Ισχύει μέχρι: 28/04/2029
   Κάτοχος Άδειας: RENAISSANCE CRYO-PRESERVATION & HEALTH CARE LIMITED
   Διεύθυνση Αλληλογραφίας: P.O.BOX 23817, 1687 Nicosia, Cyprus.

6. Αριθμός Άδειας: 019
   Ημερομηνία Έκδοσης Άδειας: 29/01/2004
   Προηγούμενη λήξη: 28/01/2024
   Ισχύει μέχρι: 28/04/2029
   Κάτοχος Άδειας: M. K. STAVRINOS LTD
   Διεύθυνση Αλληλογραφίας: P.O. BOX 21074, 1501 Nicosia, Cyprus.

Αριθμός 684

ΕΚΔΟΣΗ ΑΔΕΙΩΝ ΠΑΡΑΣΚΕΥΗΣ/ΕΙΣΑΓΩΓΗΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΠΡΟΪΟΝΤΩΝ ΑΠΟ ΤΡΙΤΕΣ ΧΩΡΕΣ

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

1. Αριθμός Άδειας: 061
   Ημερομηνία Έκδοσης Άδειας: 09/10/2023
   Ισχύει μέχρι: 08/10/2028
   Κάτοχος Άδειας: VARNAVAS HADJIPANAYIS LTD
   Διεύθυνση Αλληλογραφίας: Γιάννου Κρανιδιώτη 226, 2234 Λατσιά, Λευκωσία, Κύπρος.

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

Αριθμός 685

ΑΠΟΦΑΣΗ ΓΙΑ ΑΠΟΣΥΡΣΗ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΠΡΟΪΟΝΤΩΝ ΑΠΟ ΤΗΝ ΚΥΚΛΟΦΟΡΙΑ

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

Άρ. Άδειας Κυκλοφορίας	Όνομα Φαρμακευτικού Προϊόντος	Δραστικά Συστατικά	Κάτοχος Άδειας Κυκλοφορίας	Ημερομηνία Έκδοσης Άδειας	Παρτίδα απόσυρσης	Λόγος Απόσυρσης
N/A	Mydriaticum Stull eye Drops	Tropicamid	Pharma Stulln GmbH	N/A	22K048	Βάση του άρθρου 51.1

Αριθμός 686

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 INHALATION SOLUTION, PRESSURISED 20MCG/DOSE	PI0043	KRINERA HEALTH LTD	27/09/2023
BUSCOPAN PLUS TABLET, FILM COATED 500MG/10MG	PI0064	PHARMAFAST LTD	27/09/2023
CONTROLOC TABLET, GASTRO-RESISTANT 40MG	PI0072	PHARMAFAST LTD	27/09/2023
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	PI0057	PHARMAFAST LTD	27/09/2023
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	PI0056	PHARMAFAST LTD	27/09/2023
FLIXOTIDE INHALER 50MCG	PI0037	KRINERA HEALTH LTD	27/09/2023
PARIET TABLET, GASTRO-RESISTANT 20MG	PI0061	PHARMAFAST LTD	27/09/2023
SEROXAT TABLET, FILM COATED 20MG	PI0076	PHARMAFAST LTD	27/09/2023
ZOLOFT TABLET, FILM COATED 100MG	PI0059	PHARMAFAST LTD	27/09/2023
ZOLOFT TABLET, FILM COATED 50MG	PI0058	PHARMAFAST LTD	27/09/2023
ZOVIRAX CREAM 5% W/W	PI0065	PHARMAFAST LTD	27/09/2023

Αριθμός 687

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
023554	40M0200	BAYER HELLAS ABEE	Επ' αόριστον
022174	35M0017	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	Επ' αόριστον
022504	37M0015	FERRING HELLAS MEPE	Επ' αόριστον
022503	37M0014	FERRING HELLAS MEPE	Επ' αόριστον
023695	41M0146	LABORATOIRES BESINS INTERNATIONAL	Επ' αόριστον
023009	37M0054	NORIDEM ENTERPRISES LTD	Επ' αόριστον
023010	37M0055	NORIDEM ENTERPRISES LTD	Επ' αόριστον
023011	39M0054	AUROBINDO PHARMA (MALTA) LIMITED	Επ' αόριστον
023220	39M0068	BAUSCH + LOMB IRELAND LIMITED	Επ' αόριστον
023101	38M0213	MEDOCHEMIE LTD	Επ' αόριστον
022680	36M0099	MEDOCHEMIE LTD	Επ' αόριστον
023599	34M0264	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022648	35M0156	ACTIVASE PHARMACEUTICALS LTD	Επ' αόριστον
022649	35M0157	ACTIVASE PHARMACEUTICALS LTD	Επ' αόριστον
023051	36M0200	NORIDEM ENTERPRISES LTD	Επ' αόριστον
023052	36M0201	NORIDEM ENTERPRISES LTD	Επ' αόριστον
022991	38M0082	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
022989	38M0080	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
022990	38M0081	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
022988	38M0079	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	Επ' αόριστον
023281	37M0133	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	Επ' αόριστον
023820	34M0233	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023821	34M0234	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023813	42M0146	CASEN RECORDATI SL	Επ' αόριστον
023812	42M0145	CASEN RECORDATI SL	Επ' αόριστον
022813	37M0160	JOHNSON & JOHNSON HELLAS CONSUMER AE	Επ' αόριστον
023756	41M0152	VENIPHARM	Επ' αόριστον
023752	41M0148	VENIPHARM	Επ' αόριστον
023753	41M0149	VENIPHARM	Επ' αόριστον
023754	41M0150	VENIPHARM	Επ' αόριστον
023755	41M0151	VENIPHARM	Επ' αόριστον
022717	37M0029	RECKITT BENCKISER HELLAS HEALTHCARE SA	Επ' αόριστον

023330	37M0113	PHARMATHEN S.A.	Επ' αόριστον
023331	37M0117	PHARMATHEN S.A.	Επ' αόριστον
023329	37M0112	PHARMATHEN S.A.	Επ' αόριστον
022735	36M0094	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	Επ' αόριστον
022734	36M0093	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	Επ' αόριστον
022498	33M0175	JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
023093	36M0134	GENEPHARM SA	Επ' αόριστον
023092	36M0133	GENEPHARM SA	Επ' αόριστον
023654	40M0241	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	Επ' αόριστον
023833	42M0134	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
023830	42M0131	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
023831	42M0132	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
023832	42M0133	ELPEN PHARMACEUTICAL CO INC	Επ' αόριστον
022925	38M0072	OCTAPHARMA (IP) SPRL	Επ' αόριστον
023146	38M0006	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023147	38M0007	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023150	38M0093	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023151	38M0094	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023148	38M0091	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023149	38M0092	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
023722	42M0016	PHARMAZAC S.A.	Επ' αόριστον
021201	29M0319	PHARMATHEN S.A.	Επ' αόριστον
021199	29M0317	PHARMATHEN S.A.	Επ' αόριστον
021200	29M0318	PHARMATHEN S.A.	Επ' αόριστον
023145	38M0111	AOP ORPHAN PHARMACEUTICALS GMBH	Επ' αόριστον
022982	38M0024	MEDOCHEMIE LTD	Επ' αόριστον
022501	36M0213	EUROCEPT INTERNATIONAL B.V	Επ' αόριστον
022788	36M0098	VENIFAR LTD	Επ' αόριστον
023215	38M0126	BAXTER (HELLAS) EPE	Επ' αόριστον
023798	42M0080	MEDIS GMBH	Επ' αόριστον
023431	40M0100	STADA ARZNEIMITTEL AG	Επ' αόριστον
022835	37M0152	VIANEX S.A	Επ' αόριστον
023084	37M0179	ACCORD HEALTHCARE S.L.U	Επ' αόριστον
022677	36M0044	DEMO S.A.	Επ' αόριστον
022678	36M0045	DEMO S.A.	Επ' αόριστον
022679	36M0046	DEMO S.A.	Επ' αόριστον
022676	36M0043	DEMO S.A.	Επ' αόριστον
022255	3300197	ALZEDEM TABLET, FILM COATED 10MG	Επ' αόριστον
022256	3300198	ALZEDEM TABLET, FILM COATED 15MG	Επ' αόριστον
022257	3300199	ALZEDEM TABLET, FILM COATED 20MG	Επ' αόριστον
022254	3300196	ALZEDEM TABLET, FILM COATED 5MG	Επ' αόριστον
022854	3700161	ASPIRIN EC TABLET, GASTRO-RESISTANT 100MG	Επ' αόριστον
022932	3800218	ASPRO CLEAR EFFERVESCENT TABLET 300MG	Επ' αόριστον
022882	3700121	ATAZANAVIR REMEDICA CAPSULE, HARD 100MG	Επ' αόριστον
022883	3700122	ATAZANAVIR REMEDICA CAPSULE, HARD 150MG	Επ' αόριστον

022884	3700123	ATAZANAVIR REMEDICA CAPSULE, HARD 200MG	Επ' αόριστον
022885	3700124	ATAZANAVIR REMEDICA CAPSULE, HARD 300MG	Επ' αόριστον
022952	3700129	FLAMATAN TABLET, FILM COATED 12.5MG	Επ' αόριστον
022869	3500143	FRUTENOR SOLUTION FOR INJECTION OR INFUSION 1G/5ML	Επ' αόριστον
022848	3700134	REFETIB TABLET, FILM COATED 250MG	Επ' αόριστον
022939	3700144	ROSUVASTATIN ACINO TABLET, FILM COATED 10MG	Επ' αόριστον
022940	3700145	ROSUVASTATIN ACINO TABLET, FILM COATED 20MG	Επ' αόριστον
022941	3700146	ROSUVASTATIN ACINO TABLET, FILM COATED 40MG	Επ' αόριστον
022938	3700143	ROSUVASTATIN ACINO TABLET, FILM COATED 5MG	Επ' αόριστον
022935	3800140	STATOL TABLET, FILM COATED 10MG	Επ' αόριστον
022936	3800141	STATOL TABLET, FILM COATED 20MG	Επ' αόριστον
022937	3800142	STATOL TABLET, FILM COATED 40MG	Επ' αόριστον
022934	3800139	STATOL TABLET, FILM COATED 5MG	Επ' αόριστον
022561	3600117	TIVEL TABLET 1MG	Επ' αόριστον
022852	3700053	TYBETA TABLET, FILM COATED 100MG	Επ' αόριστον
022850	3700051	TYBETA TABLET, FILM COATED 25MG	Επ' αόριστον
022851	3700052	TYBETA TABLET, FILM COATED 50MG	Επ' αόριστον
022837	3600118	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	Επ' αόριστον
022900	3700045	ZIRCOS TABLET, FILM COATED 10MG	Επ' αόριστον
022901	3700046	ZIRCOS TABLET, FILM COATED 20MG	Επ' αόριστον
022899	3700044	ZIRCOS TABLET, FILM COATED 5MG	Επ' αόριστον

Αριθμός 688

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: 029
   Ημερομηνία Έκδοσης Άδειας: 15/10/2003
   Προηγούμενη λήξη: 14/10/2023
   Ισχύει μέχρι: 14/10/2028
   Κάτοχος Άδειας: REMEDICA LTD
   Διεύθυνση Αλληλογραφίας: Τ. Κ. 51706, 3508 Λεμεσός, Κύπρος.

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

Αριθμός 689

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
43S0028	AMBISOME LIPOSOMAL POWDER FOR DISPERSION FOR INFUSION 50MG/VIAL	AMPHOTERICIN B	GILEAD SCIENCES HELLAS M.E.P.E.	22/11/2023
43S0008	DOXYCYCLINE TZF SOLUTION FOR INFUSION 20MG/ML	DOXYCYCLINE	TARCHOMINSKIE ZAKLADY FARMACEUTYCZNE POLFA SPOLKA AKCYJNA	27/09/2023
43S0003	HEPARIN GILVASAN SOLUTION FOR INJECTION 100IU/ML	HEPARIN SODIUM	GILVASAN PHARMA GMBH	27/09/2023
43S0005	MENI-DROPS EYE DROPS, SOLUTION 0.25MG/ML	KETOTIFEN FUMARATE	PHARMEX S.A.	27/09/2023
43S0004	PHARMEXIN EYE DROPS, SOLUTION 0.2 % W/V (2MG/ML)	BRIMONIDINE TARTRATE	PHARMEX S.A.	27/09/2023
43S0006	PROTAMINE SULFATE SOLUTION FOR INJECTION 10MG/ML	PROTAMINE SULFATE	WOCKHARDT UK LTD	27/09/2023
43S0013	RIFAMAZID CAPSULE, HARD 300MG+150MG	ISONIAZID	TARCHOMINSKIE ZAKLADY FARMACEUTYCZNE POLFA SPOLKA AKCYJNA	27/09/2023
43S0013	RIFAMAZID CAPSULE, HARD 300MG+150MG	RIFAMPICIN	TARCHOMINSKIE ZAKLADY FARMACEUTYCZNE POLFA SPOLKA AKCYJNA	27/09/2023
43S0012	VERILIGO NASAL SPRAY, SOLUTION 10MG/DOSE	METOCLOPRAMIDE HYDROCHLORIDE	VERISFIELD SINGLE MEMBER S.A.	27/09/2023

Αριθμός 690

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: 040
   Ημερομηνία Έκδοσης Άδειας: 25/9/2023
   Ισχύει μέχρι: 24/9/2028
   Κάτοχος Άδειας: RSL REVOLUTIONARY LABS LTD
   Διεύθυνση Αλληλογραφίας: Αλκιδάμου 1, Hi-Tech Cluster, Άγιος Αθανάσιος, 4101 Λεμεσός.

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

Αριθμός 691

ΑΔΕΙΕΣ ΚΥΚΛΟΦΟΡΙΑΣ ΠΟΥ ΕΧΟΥΝ ΕΚΔΟΘΕΙ ΑΠΟ ΤΟ ΣΥΜΒΟΥΛΙΟ ΦΑΡΜΑΚΩΝ

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

Άρ. Άδειας Κυκλοφορίας	Όνομα Φαρμακευτικού Προϊόντος	Δραστικά Συστατικά	Κάτοχος Άδειας Κυκλοφορίας	Ημερομηνία Έκδοσης Άδειας
023852	AXITINIB/SANDOZ TABLET, FILM COATED 1MG	AXITINIB	SANDOZ PHARMACEUTICALS D.D.	01/08/2023
023853	AXITINIB/SANDOZ TABLET, FILM COATED 5MG	AXITINIB	SANDOZ PHARMACEUTICALS D.D.	01/08/2023
023854	ENKIA TABLET, FILM COATED 15MG	RIVAROXABAN	MEDOCHEMIE LTD	01/08/2023
023855	ENKIA TABLET, FILM COATED 20MG	RIVAROXABAN	MEDOCHEMIE LTD	01/08/2023
023863	METHOTREXATE SOLUTION FOR INJECTION 500MG/20ML	METHOTREXATE	PFIZER HELLAS AE	01/08/2023
023862	METHOTREXATE SOLUTION FOR INJECTION 50MG/2ML	METHOTREXATE	PFIZER HELLAS AE	01/08/2023
023857	TELMISARTAN JUBILANT TABLET 20MG	TELMISARTAN	JUBILANT PHARMACEUTICALS NV	01/08/2023
023858	TELMISARTAN JUBILANT TABLET 40MG	TELMISARTAN	JUBILANT PHARMACEUTICALS NV	01/08/2023
023859	TELMISARTAN JUBILANT TABLET 80MG	TELMISARTAN	JUBILANT PHARMACEUTICALS NV	01/08/2023
023906	CLEENEMA RECTAL SOLUTION (180.8MG/79.9MG)/ML	DISODIUM PHOSPHATE DODECAHYDRATE	CASEN RECORDATI SL	01/12/2023
023906	CLEENEMA RECTAL SOLUTION (180.8MG/79.9MG)/ML	SODIUM DIHYDROGEN PHOSPHATE DIHYDRATE	CASEN RECORDATI SL	01/12/2023
023873	PIRFENIDONE ACCORD TABLET, FILM COATED 267MG	PIRFENIDONE	ACCORD HEALTHCARE S.L.U	04/10/2023
023874	PIRFENIDONE ACCORD TABLET, FILM COATED 801MG	PIRFENIDONE	ACCORD HEALTHCARE S.L.U	04/10/2023
023840	ABIRATERONE/SANDOZ TABLET, FILM COATED 500MG	ABIRATERONE ACETATE	SANDOZ PHARMACEUTICALS D.D.	05/07/2023
023839	DUOMAX ORAL SUSPENSION (160MG/48MG)/5ML	IBUPROFEN	MEDOCHEMIE LTD	06/07/2023
023839	DUOMAX ORAL SUSPENSION (160MG/48MG)/5ML	PARACETAMOL	MEDOCHEMIE LTD	06/07/2023
023907	BUDOSAN SUPPOSITORY 4MG	BUDESONIDE	DR. FALK PHARMA GMBH	07/12/2023
023841	SUGAMMADEX MSN SOLUTION FOR INJECTION 100MG/ML	SUGAMMADEX SODIUM	MSN LABS EUROPE LIMITED	10/07/2023
023860	ONDANSETRON/KABI SOLUTION FOR INFUSION 0.08MG/ML	ONDANSETRON HYDROCHLORIDE DIHYDRATE	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	10/08/2023
023861	ONDANSETRON/KABI SOLUTION FOR INFUSION 0.16MG/ML	ONDANSETRON HYDROCHLORIDE DIHYDRATE	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	10/08/2023

023847	PEMETREXED SANDOZ CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	PEMETREXED DISODIUM HEMIPENTAHYDRATE	SANDOZ PHARMACEUTICALS D.D.	12/07/2023
023912	BRALTUS INHALATION POWDER, HARD CAPSULE 10MCG	TIOTROPIUM BROMIDE MONOHYDRATE	TEVA BV	13/12/2023
023914	SUGAMMADEX/STADA SOLUTION FOR INJECTION 100MG/ML	SUGAMMADEX SODIUM	STADA ARZNEIMITTEL AG	13/12/2023
023846	JIVOLAR TABLET, FILM COATED 50MG/1000MG	METFORMIN HYDROCHLORIDE	MEDOCHEMIE LTD	14/07/2023
023846	JIVOLAR TABLET, FILM COATED 50MG/1000MG	SITAGLIPTIN PHOSPHATE MONOHYDRATE	MEDOCHEMIE LTD	14/07/2023
023845	JIVOLAR TABLET, FILM COATED 50MG/850MG	METFORMIN HYDROCHLORIDE	MEDOCHEMIE LTD	14/07/2023
023845	JIVOLAR TABLET, FILM COATED 50MG/850MG	SITAGLIPTIN PHOSPHATE MONOHYDRATE	MEDOCHEMIE LTD	14/07/2023
023913	NUROFEN LIQUID CAPSULES EXTRA CAPSULE, SOFT 400MG	IBUPROFEN	RECKITT BENCKISER HELLAS HEALTHCARE SA	14/12/2023
023895	DOLTEN TABLET, FILM COATED 100MG	TAPENTADOL HYDROCHLORIDE	MEDOCHEMIE LTD	15/11/2023
023893	DOLTEN TABLET, FILM COATED 50MG	TAPENTADOL HYDROCHLORIDE	MEDOCHEMIE LTD	15/11/2023
023894	DOLTEN TABLET, FILM COATED 75MG	TAPENTADOL HYDROCHLORIDE	MEDOCHEMIE LTD	15/11/2023
023897	FEREMAZOL TABLET, FILM COATED 2.5MG	LETROZOLE	REMEDICA LTD	15/11/2023
023896	LEVOSIMENDAN WIN MEDICA CONCENTRATE FOR SOLUTION FOR INFUSION 2.5MG/ML	LEVOSIMENDAN	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	15/11/2023
023900	MIDODRINE TILLOMED TABLET 2.5MG	MIDODRINE HYDROCHLORIDE	TILLOMED PHARMA GMBH.	15/11/2023
023901	MIDODRINE TILLOMED TABLET 5MG	MIDODRINE HYDROCHLORIDE	TILLOMED PHARMA GMBH.	15/11/2023
023899	SERTRALINE ACCORD TABLET, FILM COATED 100MG	SERTRALINE HYDROCHLORIDE	ACCORD HEALTHCARE S.L.U	15/11/2023
023898	SERTRALINE ACCORD TABLET, FILM COATED 50MG	SERTRALINE HYDROCHLORIDE	ACCORD HEALTHCARE S.L.U	15/11/2023
023909	RIVAROXABAN PHARMAZAC TABLET, FILM COATED 10MG	RIVAROXABAN	PHARMAZAC S.A.	15/12/2023
023910	RIVAROXABAN PHARMAZAC TABLET, FILM COATED 15MG	RIVAROXABAN	PHARMAZAC S.A.	15/12/2023
023908	RIVAROXABAN PHARMAZAC TABLET, FILM COATED 2.5MG	RIVAROXABAN	PHARMAZAC S.A.	15/12/2023
023911	RIVAROXABAN PHARMAZAC TABLET, FILM COATED 20MG	RIVAROXABAN	PHARMAZAC S.A.	15/12/2023
023842	RIVAROXABAN/SANDOZ TABLET, FILM COATED 10MG	RIVAROXABAN	SANDOZ PHARMACEUTICALS D.D.	17/07/2023
023843	RIVAROXABAN/SANDOZ TABLET, FILM COATED 15MG	RIVAROXABAN	SANDOZ PHARMACEUTICALS D.D.	17/07/2023
023844	RIVAROXABAN/SANDOZ TABLET, FILM COATED 20MG	RIVAROXABAN	SANDOZ PHARMACEUTICALS D.D.	17/07/2023

023891	AZEMISTA NASAL SPRAY, SUSPENSION (137MCG/50MCG)/ACTUATION	AZELASTINE HYDROCHLORIDE	ELPEN PHARMACEUTICAL CO INC	20/10/2023
023891	AZEMISTA NASAL SPRAY, SUSPENSION (137MCG/50MCG)/ACTUATION	FLUTICASONE PROPIONATE	ELPEN PHARMACEUTICAL CO INC	20/10/2023
023892	TERUMA TABLET, FILM COATED 14MG	TERIFLUNOMIDE	TEVA BV	20/10/2023
023851	ELYMBUS EYE GEL SINGLE-DOSE CONTAINER 0.1 MG/G	BIMATOPROST	LABORATOIRES THEA	21/07/2023
023850	SIMEVIN TABLET, FILM COATED 50MG/1000MG	METFORMIN HYDROCHLORIDE	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	21/07/2023
023850	SIMEVIN TABLET, FILM COATED 50MG/1000MG	SITAGLIPTIN HYDROCHLORIDE	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	21/07/2023
023849	SIMEVIN TABLET, FILM COATED 50MG/850MG	METFORMIN HYDROCHLORIDE	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	21/07/2023
023849	SIMEVIN TABLET, FILM COATED 50MG/850MG	SITAGLIPTIN HYDROCHLORIDE	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	21/07/2023
023869	PROLUTEX SOLUTION FOR INJECTION IN PREFILLED SYRINGE 25MG	PROGESTERONE	IBSA FARMACEUTICI ITALIA SRL	21/09/2023
023916	AMBRISENTAN MSN TABLET, FILM COATED 10MG	AMBRISENTAN	MSN LABS EUROPE LIMITED	21/12/2023
023915	AMBRISENTAN MSN TABLET, FILM COATED 5MG	AMBRISENTAN	MSN LABS EUROPE LIMITED	21/12/2023
023872	AZACITIDINE/SANDOZ POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	AZACITIDINE	SANDOZ PHARMACEUTICALS D.D.	22/09/2023
023864	ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	ERLOTINIB HYDROCHLORIDE	SANDOZ GMBH	23/08/2023
023866	XABAREM TABLET, FILM COATED 10MG	RIVAROXABAN	REMEDICA LTD	23/08/2023
023867	XABAREM TABLET, FILM COATED 15MG	RIVAROXABAN	REMEDICA LTD	23/08/2023
023865	XABAREM TABLET, FILM COATED 2.5MG	RIVAROXABAN	REMEDICA LTD	23/08/2023
023868	XABAREM TABLET, FILM COATED 20MG	RIVAROXABAN	REMEDICA LTD	23/08/2023
023870	NORADRENALINE ALTAN SOLUTION FOR INFUSION 0.04MG/ML	NORADRENALINE TARTRATE	ALTAN PHARMACEUTICALS S.A.	25/09/2023
023871	NUOVOPAN SOLUTION FOR INJECTION OR INFUSION 20MG/2ML	NEFOPAM HYDROCHLORIDE	MEDOCHEMIE IBERIA S.A.	25/09/2023
023905	DEXMEDETOMIDINE EVER VALINJECT CONCENTRATE FOR SOLUTION FOR INFUSION 100MCG/ML	DEXMEDETOMIDINE HYDROCHLORIDE	EVER VALINJECT GMBH	28/09/2023
023904	FINGOLIMOD/STADA CAPSULE, HARD 0.5MG	FINGOLIMOD HYDROCHLORIDE	STADA ARZNEIMITTEL AG	28/11/2023

023856	BILAZ TABLET, ORODISPERSIBLE 20MG	BILASTINE	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	31/07/2023
023902	ZESTAVAL TABLET 400MG	ALBENDAZOLE 400.00 mg	REMEDICA LTD	15/11/2023
023903	NASOFLU NASAL SPRAY, SUSPENSION 50MCG	FLUTICASONE PROPIONATE 50.00 µg	SAPIENS PHARMACEUTICALS LTD	22/11/2023
023889	AMBRISENTAN SAPIENS TABLET, FILM COATED 10MG	AMBRISENTAN 10.00 mg	SAPIENS PHARMACEUTICALS LTD	27/09/2023
023888	AMBRISENTAN SAPIENS TABLET, FILM COATED 5MG	AMBRISENTAN 5.00 mg	SAPIENS PHARMACEUTICALS LTD	27/09/2023
023890	CEFTRIAXONE SAPIENS POWDER FOR SOLUTION FOR INFUSION 1000MG/VIAL	CEFTRIAXONE SODIUM 1193.00 mg	SAPIENS PHARMACEUTICALS LTD	27/09/2023
023885	DAPTOMYCIN SAPIENS POWDER FOR SOLUTION FOR INJECTION/INFUSION 350MG/VIAL	DAPTOMYCIN 350.00 mg	SAPIENS PHARMACEUTICALS LTD	27/09/2023
023882	ENDREM CAPSULE, HARD 125MG	APREPITANT 125.00 mg	REMEDICA LTD	27/09/2023
023883	ENDREM CAPSULE, HARD 125MG+80MG	APREPITANT 125.00 mg | APREPITANT 80.00 mg	REMEDICA LTD	27/09/2023
023881	ENDREM CAPSULE, HARD 80MG	APREPITANT 80.00 mg	REMEDICA LTD	27/09/2023
023878	EUTHYROX TABLET 25MCG	LEVOTHYROXINE SODIUM 25.00 µg	MERCK A E HELLAS	27/09/2023
023879	EUTHYROX TABLET 75MCG	LEVOTHYROXINE SODIUM 75.00 µg	MERCK A E HELLAS	27/09/2023
023876	GUPERUL TABLET 10MG	TORASEMIDE 10.00 mg	VERISFIELD SINGLE MEMBER S.A.	27/09/2023
023877	GUPERUL TABLET 20MG	TORASEMIDE 20.00 mg	VERISFIELD SINGLE MEMBER S.A.	27/09/2023
023875	GUPERUL TABLET 5MG	TORASEMIDE 5.00 mg	VERISFIELD SINGLE MEMBER S.A.	27/09/2023
023886	INFIREM TABLET, FILM COATED 30MG	DAPOXETINE HYDROCHLORIDE 33.584 mg	REMEDICA LTD	27/09/2023
023887	INFIREM TABLET, FILM COATED 60MG	DAPOXETINE HYDROCHLORIDE 67.168 mg	REMEDICA LTD	27/09/2023
023880	MONOCLOX POWDER FOR SOLUTION FOR INJECTION/INFUSION 2G	CLOXACILLIN 2.00 g	MEDOCHEMIE LTD	27/09/2023
023884	MUPIDERM CREAM 2% W/W	MUPIROCIN CALCIUM 0.3225 g	KLEVA PHARMACEUTICALS S.A. (TRADING AS KLEVA S.A.)	27/09/2023

Αριθμός 692

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
PI0117	CONCOR TABLET, FILM COATED 5MG	BISOPROLOL FUMARATE 5.00 mg	FAMAR LYON	27/09/2023
PI0117	CONCOR TABLET, FILM COATED 5MG	BISOPROLOL FUMARATE 5.00 mg	GN NEOHEALTH LTD	27/09/2023
PI0117	CONCOR TABLET, FILM COATED 5MG	BISOPROLOL FUMARATE 5.00 mg	MARIO D. KATSIKAS S.A.	27/09/2023
PI0117	CONCOR TABLET, FILM COATED 5MG	BISOPROLOL FUMARATE 5.00 mg	MERCK HEALTHCARE KGAA	27/09/2023
PI0117	CONCOR TABLET, FILM COATED 5MG	BISOPROLOL FUMARATE 5.00 mg	MERCK S.L.U.	27/09/2023
PI0117	CONCOR TABLET, FILM COATED 5MG	BISOPROLOL FUMARATE 5.00 mg	PHARMAFAST LTD	27/09/2023
PI0117	CONCOR TABLET, FILM COATED 5MG	BISOPROLOL FUMARATE 5.00 mg	PHARMASERVICE SA	27/09/2023
PI0117	CONCOR TABLET, FILM COATED 5MG	BISOPROLOL FUMARATE 5.00 mg	PHARMASTOCK S.A.	27/09/2023
PI0117	CONCOR TABLET, FILM COATED 5MG	BISOPROLOL FUMARATE 5.00 mg	PRIMEPHARM	27/09/2023
PI0118	CIPRALEX TABLET, FILM COATED 10MG	ESCITALOPRAM OXALATE 12.77 mg	GN NEOHEALTH LTD	27/09/2023
PI0118	CIPRALEX TABLET, FILM COATED 10MG	ESCITALOPRAM OXALATE 12.77 mg	H.LUNDBECK A/S	27/09/2023
PI0118	CIPRALEX TABLET, FILM COATED 10MG	ESCITALOPRAM OXALATE 12.77 mg	MARIO D. KATSIKAS S.A.	27/09/2023
PI0118	CIPRALEX TABLET, FILM COATED 10MG	ESCITALOPRAM OXALATE 12.77 mg	PHARMAFAST LTD	27/09/2023
PI0118	CIPRALEX TABLET, FILM COATED 10MG	ESCITALOPRAM OXALATE 12.77 mg	PHARMASERVICE SA	27/09/2023
PI0118	CIPRALEX TABLET, FILM COATED 10MG	ESCITALOPRAM OXALATE 12.77 mg	PHARMASTOCK S.A.	27/09/2023
PI0118	CIPRALEX TABLET, FILM COATED 10MG	ESCITALOPRAM OXALATE 12.77 mg	PRIMEPHARM	27/09/2023
PI0119	SEROPRAM TABLET, FILM COATED 20MG	CITALOPRAM HYDROBROMIDE 24.98 mg	GN NEOHEALTH LTD	27/09/2023

PI0119	SEROPRAM TABLET, FILM COATED 20MG	CITALOPRAM HYDROBROMIDE 24.98 mg	H.LUNDBECK A/S	27/09/2023
PI0119	SEROPRAM TABLET, FILM COATED 20MG	CITALOPRAM HYDROBROMIDE 24.98 mg	MARIO D. KATSIKAS S.A.	27/09/2023
PI0119	SEROPRAM TABLET, FILM COATED 20MG	CITALOPRAM HYDROBROMIDE 24.98 mg	PHARMAFAST LTD	27/09/2023
PI0119	SEROPRAM TABLET, FILM COATED 20MG	CITALOPRAM HYDROBROMIDE 24.98 mg	PHARMASERVICE SA	27/09/2023
PI0119	SEROPRAM TABLET, FILM COATED 20MG	CITALOPRAM HYDROBROMIDE 24.98 mg	PHARMASTOCK S.A.	27/09/2023
PI0119	SEROPRAM TABLET, FILM COATED 20MG	CITALOPRAM HYDROBROMIDE 24.98 mg	PRIMEPHARM	27/09/2023
PI0120	COVERSYL TABLET, FILM COATED 10MG	PERINDOPRIL ARGININE 10.00 mg	KRINERA HEALTH LTD	27/09/2023
PI0120	COVERSYL TABLET, FILM COATED 10MG	PERINDOPRIL ARGININE 10.00 mg	LIAFARM PHARMACEUTICALS SA	27/09/2023
PI0120	COVERSYL TABLET, FILM COATED 10MG	PERINDOPRIL ARGININE 10.00 mg	MARVIFARM S.A.	27/09/2023
PI0120	COVERSYL TABLET, FILM COATED 10MG	PERINDOPRIL ARGININE 10.00 mg	MEDICAMERC S.A PHARMACEUTICALS	27/09/2023
PI0120	COVERSYL TABLET, FILM COATED 10MG	PERINDOPRIL ARGININE 10.00 mg	PHARMASERVICE SA	27/09/2023
PI0120	COVERSYL TABLET, FILM COATED 10MG	PERINDOPRIL ARGININE 10.00 mg	SERVIER (IRELAND) INDUSTRIES LTD (SII)	27/09/2023
PI0121	COVERSYL TABLET, FILM COATED 5MG	PERINDOPRIL ARGININE 5.00 mg	KRINERA HEALTH LTD	27/09/2023
PI0121	COVERSYL TABLET, FILM COATED 5MG	PERINDOPRIL ARGININE 5.00 mg	LIAFARM PHARMACEUTICALS SA	27/09/2023
PI0121	COVERSYL TABLET, FILM COATED 5MG	PERINDOPRIL ARGININE 5.00 mg	MARVIFARM S.A.	27/09/2023
PI0121	COVERSYL TABLET, FILM COATED 5MG	PERINDOPRIL ARGININE 5.00 mg	MEDICAMERC S.A PHARMACEUTICALS	27/09/2023
PI0121	COVERSYL TABLET, FILM COATED 5MG	PERINDOPRIL ARGININE 5.00 mg	PHARMASERVICE SA	27/09/2023
PI0121	COVERSYL TABLET, FILM COATED 5MG	PERINDOPRIL ARGININE 5.00 mg	SERVIER (IRELAND) INDUSTRIES LTD (SII)	27/09/2023

Αριθμός 693

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
ADRIBLASTINA SOLUTION FOR INJECTION 2MG/ML	PFIZER HELLAS AE	S00524	22/11/2023
ALCAINE EYE DROPS, SOLUTION 5MG/ML	ALCON LABORATORIES HELLAS SINGLE MEMBER SACI	S00116	27/09/2023
ARTICLOX SOLUTION FOR INJECTION 1MG/2ML	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	S01183	27/09/2023
ATOSIBAN ALTAN CONCENTRATE FOR SOLUTION FOR INFUSION 37.5MG/5ML	ALTAN PHARMACEUTICALS S.A.	S01264	22/11/2023
ATOSIBAN ALTAN SOLUTION FOR INJECTION 6.75MG/0.9ML	ALTAN PHARMACEUTICALS S.A.	S01263	22/11/2023
BETRIMINE SOLUTION FOR INJECTION	HELP S.A.	S00825	27/09/2023
CYCLOGYL EYE DROPS, SOLUTION 10MG/ML	ALCON LABORATORIES HELLAS SINGLE MEMBER SACI	S00117	27/09/2023
DALACIN C CAPSULE, HARD 300MG	PFIZER HELLAS AE	S00085	27/09/2023
DISTRANEURIN CAPSULE, SOFT 192MG	CHEPLAPHARM ARZNEIMITTEL GMBH.	S01176	27/09/2023
DONARTHRIL POWDER FOR ORAL SOLUTION 1500MG/SACHET	RAFARM S.A.	S00646	27/09/2023
DOSTINEX TABLET 0,5MG	PFIZER HELLAS AE	S00641	27/09/2023
DRESPLAN TABLET 5MG	ARAFARMA GROUP S.A.	S01182	27/09/2023
ENCORTON TABLET 20MG	ADAMED PHARMA S.A.	S01117	22/11/2023
EPANUTIN SOLUTION FOR INJECTION 50MG/ML	VIATRIS HELLAS LTD	S00378	27/09/2023
FLECARDIA CAPSULE, HARD, PROLONGED-RELEASE 100MG	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	S01068	27/09/2023
FLECARDIA CAPSULE, HARD, PROLONGED-RELEASE 200MG	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	S01064	27/09/2023
FLEELAXAT ORAL SOLUTION	COOPER PHARMACEUTICALS SA (COOPER S.A.)	S00985	22/11/2023
FLUMAZENIL ALTAN SOLUTION FOR INJECTION 0.1MG/ML	ALTAN PHARMACEUTICALS S.A.	S01118	27/09/2023
FUCIDIN OINTMENT 20MG/G	LEO PHARMA A/S	S01181	27/09/2023
GLYCOPHOS CONCENTRATE FOR SOLUTION FOR INFUSION 216MG/ML	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	S01001	22/11/2023
HIPNOSEDON TABLET, FILM COATED 1MG	FARMASYN S.A.	S00090	27/09/2023
HYDROCORTISONUM-SF TABLET 10MG	SUN-FARM SP. Z.O.O	S01127	27/09/2023
IMIPENEM + CILASTATINA VENUS PHARMA POWDER FOR SOLUTION FOR INFUSION 500MG + 500MG	VENUS PHARMA GMBH	S00786	27/09/2023

IMURAN TABLET, FILM COATED 50MG	ASPEN PHARMA TRADING LIMITED	S01177	27/09/2023
INTERMED XYLOJELL SPRAY 10% W/V	IOULIA AND IRENE TSETI PHARMACEUTICAL LABORATORIES S.A.	S01267	22/11/2023
LENTOCILIN S 1200 POWDER FOR SUSPENSION FOR INJECTION 1200000IU/4ML	LABORATORIOS ATRAL S.A.	S01119	27/09/2023
LEXOTANIL TABLET 1.5MG	CHEPLAPHARM ARZNEIMITTEL GMBH.	S00087	27/09/2023
LEXOTANIL TABLET 3MG	CHEPLAPHARM ARZNEIMITTEL GMBH.	S00088	27/09/2023
LEXOTANIL TABLET 6MG	CHEPLAPHARM ARZNEIMITTEL GMBH.	S00089	27/09/2023
MEGACE TABLET 160MG	BAUSCH HEALTH IRELAND LIMITED	S01178	27/09/2023
MYCOMYCEN VAGINAL CREAM 1% W/W	VERISFIELD SINGLE MEMBER S.A.	S00796	27/09/2023
MYCOMYCEN VAGINAL SUPPOSITORIES 100MG	VERISFIELD SINGLE MEMBER S.A.	S00806	27/09/2023
NAFLOXIN EYE DROPS, SOLUTION 0.3%	COOPER PHARMACEUTICALS SA (COOPER S.A.)	S00966	22/11/2023
PAROTICIN EAR DROPS	ADELCO-CHROMATOURGIA ATHINON E.COLOCOTRONIS BROS S.A	S00778	27/09/2023
PETHIDINE HYDROCHLORIDE ALTAN SOLUTION FOR INJECTION 50MG/ML	ALTAN PHARMACEUTICALS S.A.	S01259	27/09/2023
POLYGYNAX VAGINAL CAPSULES	LABORATOIRE INNOTECH INTERNATIONAL	S01045	27/09/2023
POTASSIUM CHLORIDE/VIOSER SOLUTION FOR INJECTION 10%	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	S00061	27/09/2023
PROSTIN E2 VAGINAL GEL 2MG	PFIZER HELLAS AE	S01186	27/09/2023
PROTHURIL TABLET 50MG	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	S00496	27/09/2023
SALAZIDIN GR TABLET, GASTRO-RESISTANT 500MG	S.C. AC HELCOR PHARMA S.R.L.	S01120	27/09/2023
STELAZINE MODIFIED-RELEASE CAPSULE, HARD 10MG	VIANEX S.A.	S00620	27/09/2023
STELAZINE MODIFIED-RELEASE CAPSULE, HARD 2MG	VIANEX S.A.	S00619	27/09/2023
THIOPENTAL VUAB POWDER FOR SOLUTION FOR INJECTION 1G/VIAL	VUAB PHARMA A.S.	S01113	27/09/2023
TIMOGLAU EYE DROPS, SOLUTION 5MG/ML	LABORATORIO EDOL - PRODUTOS FARMACEUTICOS S.A.	S01262	22/11/2023
VITALIPID ADULT EMULSION FOR INFUSION	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	S01126	27/09/2023
WARFANT TABLET 1MG	MERCURY PHARMACEUTICALS (IRELAND) LIMITED	S00515	22/11/2023
WARFANT TABLET 3MG	MERCURY PHARMACEUTICALS (IRELAND) LIMITED	S00517	22/11/2023
WARFANT TABLET 5MG	MERCURY PHARMACEUTICALS (IRELAND) LIMITED	S00516	22/11/2023
ZAVEDOS POWDER FOR SOLUTION FOR INJECTION 5MG/VIAL	PFIZER HELLAS AE	S00497	27/09/2023
ZINERYT POWDER AND SOLVENT FOR CUTANEOUS SOLUTION (40MG/12MG)/ML	CHEPLAPHARM ARZNEIMITTEL GMBH.	S01180	27/09/2023

Αριθμός 694

ΤΡΟΠΟΠΟΙΗΣΕΙΣ ΑΔΕΙΩΝ ΚΥΚΛΟΦΟΡΙΑΣ ΠΟΥ ΕΧΟΥΝ ΕΓΚΡΙΘΕΙ ΑΠΟ ΤΟ ΣΥΜΒΟΥΛΙΟ ΦΑΡΜΑΚΩΝ

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

Όνομα φαρμακευ-τικού προϊόντος	Αρ. Άδειας Κυκλο-φορίας	Αρ. Τροποποίησης	Κάτοχος Άδειας Κυκλοφορίας	Περιγραφή Τροποποίησης
LETROZOLE TEVA TABLET, FILM COATED 2.5MG	LETROZOLE TEVA TABLET, FILM COATED 2.5MG	6377/23T	TEVA PHARMA BV	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
DELTIUS CAPSULE, HARD 25000IU	DELTIUS CAPSULE, HARD 25000IU	2605/23T	ITF HELLAS A.E.	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).
THERACAP CAPSULE, HARD 37MBq to 5.55GBq	THERACAP CAPSULE, HARD 37MBq to 5.55GBq	null	GE HEALTHCARE BUCHLER GMBH & CO KG	Type IB, B.III.2.a.1: Change in the specification for the active substance Sodium [131I] Iodide as applied by the drug product manufacturer to fully comply with the Ph. Eur
INFANRIX TETRA SUSPENSION FOR INJECTION	INFANRIX TETRA SUSPENSION FOR INJECTION	9048/23T, 9049/23T, 9050/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).1. c) Addition of a new specification parameter to the specification with its corresponding test method B.I.b).1. f) Change outside the approved specifications limits range for the active substance
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	9045/23T, 9046/23T, 9047/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b).1. c) Addition of a new specification parameter to the specification with its corresponding test method B.I.b).1. f) Change outside the approved specifications limits range for the active substance
INFANRIX TETRA SUSPENSION FOR INJECTION	INFANRIX TETRA SUSPENSION FOR INJECTION	9051/23T, 9052/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a).2. a) Minor change in the manufacturing process of the active substance Type IB procedure
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	9044/23T	SANOFI PASTEUR.	B.I.b.2.a) Minor changes to an approved test procedure
CERTICAN TABLET 0.25MG	CERTICAN TABLET 0.25MG	9783/23T	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)*
CERTICAN TABLET 1MG	CERTICAN TABLET 1MG	9782/23T	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)*
CERTICAN TABLET 0.5MG	CERTICAN TABLET 0.5MG	9781/23T	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)*
CERTICAN TABLET 0.75MG	CERTICAN TABLET 0.75MG	9780/23T	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)*
MONOPROST EYE DROPS, SOLUTION IN SINGLE DOSE CONTAINER 50MCG/ML	MONOPROST EYE DROPS, SOLUTION IN SINGLE DOSE CONTAINER 50MCG/ML	4978/23T	LABORATOIRES THEA	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
RUPAFIN TABLET 10MG	RUPAFIN TABLET 10MG	10029/23T, 10030/23T, 10031/23T	J. URIACH Y COMPANIA S.A.	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.b.5.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
MYCOPHENOLATE MOFETIL ACCORD TABLET, FILM COATED 500MG	MYCOPHENOLATE MOFETIL ACCORD TABLET, FILM COATED 500MG	5650/23T	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
FESOTERODINE ACCORD TABLET, PROLONGED-	FESOTERODINE ACCORD TABLET, PROLONGED-	8531/23T	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

RELEASE 8MG	RELEASE 8MG			product - Change in the holding time of an intermediate
STREPFEN ORANGE SUGAR FREE LOZENGE 8.75MG	STREPFEN ORANGE SUGAR FREE LOZENGE 8.75MG	7528/23T, 7529/23T, 7530/23T	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 - 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 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
STREPFEN LOZENGE 8.75MG	STREPFEN LOZENGE 8.75MG	7531/23T, 7532/23T, 7533/23T	RECKITT BENCKISER HELLAS CHEMICAL 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 - 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 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
STREPFEN DIRECT CHERRY & MINT OROMUCOSAL SPRAY 8.75MG	STREPFEN DIRECT CHERRY & MINT OROMUCOSAL SPRAY 8.75MG	7534/23T, 7535/23T, 7536/23T	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 - 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 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
FUCICORT CREAM	FUCICORT CREAM	2928/22T, 2929/22T, 2930/22T, 2931/22T, 2932/22T, 2933/22T, 2934/22T, 2935/22T, 2936/22T, 2937/22T	LEO PHARMA A/S	B.II.a.3.b.2 B.II.a.3.b.2 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Chang B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in sh B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, b B.II.b.1.b B.II.b.1.b - 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.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition o 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
SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	9368/23T, 9369/23T, 9370/23T	ASTRAZENECA 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
SYMBICORT TURBUHALER POWDER FOR INHALATION	SYMBICORT TURBUHALER POWDER FOR INHALATION	9365/23T, 9366/23T, 9367/23T	ASTRAZENECA 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

320MCG/9 MCG	320MCG/9 MCG			substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5 MCG	SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5 MCG	9374/23T, 9375/23T, 9376/23T	ASTRAZENECA 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
PANMIGRAN TABLET, FILM COATED 250MG/250 MG/65MG	PANMIGRAN TABLET, FILM COATED 250MG/250 MG/65MG	7355/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZOVIDUO CREAM (50MG/10MG)/G	ZOVIDUO CREAM (50MG/10MG)/G	7359/23T	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
PANADOL COLD & FLU & COUGH POWDER FOR ORAL SOLUTION 1000MG/200MG/12.2MG	PANADOL COLD & FLU & COUGH POWDER FOR ORAL SOLUTION 1000MG/200MG/12.2MG	7358/23T	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
PANADOL COLD & FLU & COUGH CAPSULE, HARD 500MG/100MG/6.1MG	PANADOL COLD & FLU & COUGH CAPSULE, HARD 500MG/100MG/6.1MG	7357/23T	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	OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	7356/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

			(GSK CH ΕΛΛΑΣ ΑΕ)	
DUOKOPT EYE DROPS, SOLUTION 20MG/ML+ 5MG/ML	DUOKOPT EYE DROPS, SOLUTION 20MG/ML+ 5MG/ML	9513/23T	LABORATOIR ES 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
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 22.5MG	ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 22.5MG	9530/23T	RECORDATI INDUSTRIA CHIMICA & FARMACEUTI CA S.P.A.	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 7.5MG	ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 7.5MG	9531/23T	RECORDATI INDUSTRIA CHIMICA & FARMACEUTI CA S.P.A.	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 45MG	ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 45MG	9529/23T	RECORDATI INDUSTRIA CHIMICA & FARMACEUTI CA S.P.A.	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ROZOR TABLET, FILM COATED 10MG/10M G	ROZOR TABLET, FILM COATED 10MG/10M G	9511/23T, 9512/23T	VIATRIS HEALTHCARE 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
ROZOR TABLET, FILM COATED 20MG/10M G	ROZOR TABLET, FILM COATED 20MG/10M G	9509/23T, 9510/23T	VIATRIS HEALTHCARE 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

AZITHROMYCIN ALTAN POWDER FOR SOLUTION FOR INFUSION 500MG	AZITHROMYCIN ALTAN POWDER FOR SOLUTION FOR INFUSION 500MG	5692/23T	ALTAN PHARMACEUTICALS 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
RUPAFIN ORAL SOLUTION 1MG/ML	RUPAFIN ORAL SOLUTION 1MG/ML	6838/23T	J. URIACH Y COMPANIA S.A.	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
RANOLAZINE ELC TABLET, PROLONGED-RELEASE 750MG	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 750MG	8036/23T, 8037/23T	ELC GROUP S.R.O.	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.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
RANOLAZINE ELC TABLET, PROLONGED-RELEASE 375MG	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 375MG	8040/23T, 8041/23T	ELC GROUP S.R.O.	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.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
RANOLAZINE ELC TABLET, PROLONGED-RELEASE 500MG	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 500MG	8038/23T, 8039/23T	ELC GROUP S.R.O.	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.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
BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	3633/23T, 3634/23T, 3635/23T, 3636/23T, 3637/23T, 3638/23T, 3639/23T, 3640/23T, 3641/23T, 3642/23T, 3643/23T	ABBVIE PHARMACEUTICALS S.A.	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation B.I.d.1.c B.I.d.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage per B.I.b.1.c B.I.b.1.c - QUALITY

				CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.a.1.j B.I.a.1.j - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starti 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.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific
BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	3655/23T, 3656/23T, 3657/23T, 3658/23T, 3659/23T, 3660/23T, 3661/23T, 3662/23T, 3663/23T, 3664/23T, 3665/23T	ABBVIE PHARMACEUTICALS S.A.	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation B.I.d.1.c B.I.d.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage per B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.a.1.j B.I.a.1.j - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starti 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.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific
BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	3644/23T, 3645/23T, 3646/23T, 3647/23T, 3648/23T, 3649/23T, 3650/23T, 3651/23T, 3652/23T, 3653/23T, 3654/23T	ABBVIE PHARMACEUTICALS S.A.	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation B.I.d.1.c B.I.d.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage per B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in

				the specific B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.a.1.j B.I.a.1.j - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starti 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.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	3666/23T, 3667/23T, 3668/23T, 3669/23T, 3670/23T, 3671/23T, 3672/23T, 3673/23T, 3674/23T, 3675/23T, 3676/23T	ABBVIE PHARMACEUTICALS S.A.	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation B.I.d.1.c B.I.d.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage per B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.b.2.d B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedu B.I.a.1.j B.I.a.1.j - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starti 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.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific
BOSENTAN ACCORD TABLET, FILM COATED 125MG	BOSENTAN ACCORD TABLET, FILM COATED 125MG	9576/23T	ACCORD HEALTHCARE S.L.U	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
BOSENTAN ACCORD TABLET, FILM	BOSENTAN ACCORD TABLET, FILM	9577/23T	ACCORD HEALTHCARE S.L.U	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or

COATED 62.5MG	COATED 62.5MG			starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5 ML	FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5 ML	8269/23T	GLAXOSMITHKLINE BIOLOGICALS 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
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	9392/23T, 9393/23T	OCTAPHARMA (IP) SPRL	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products
AXITINIB/SANDOZ TABLET, FILM COATED 5MG	AXITINIB/SANDOZ TABLET, FILM COATED 5MG	5662/23T	SANDOZ PHARMACEUTICALS D.D.	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
AXITINIB/SANDOZ TABLET, FILM COATED 1MG	AXITINIB/SANDOZ TABLET, FILM COATED 1MG	5663/23T	SANDOZ PHARMACEUTICALS D.D.	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
ATORVASTATIN AUROBINDO TABLET, FILM COATED 40MG	ATORVASTATIN AUROBINDO TABLET, FILM COATED 40MG	6946/23T, 6947/23T, 6948/23T	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
ATORVASTATIN AUROBINDO TABLET, FILM COATED 10MG	ATORVASTATIN AUROBINDO TABLET, FILM COATED 10MG	6952/23T, 6953/23T, 6954/23T	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
ATORVASTATIN AUROBINDO TABLET, FILM COATED 20MG	ATORVASTATIN AUROBINDO TABLET, FILM COATED 20MG	6949/23T, 6950/23T, 6951/23T	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
WILATE 500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	WILATE 500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	7487/23T, 7488/23T	OCTAPHARMA (IP) SPRL	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes B.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
WILATE 1000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	WILATE 1000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	7485/23T, 7486/23T	OCTAPHARMA (IP) SPRL	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes B.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
EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	7686/23T	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
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	9670/23T	SAPIENS 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
MYCOPHENOLATE MOFETIL ACCORD TABLET, FILM COATED 500MG	MYCOPHENOLATE MOFETIL ACCORD TABLET, FILM COATED 500MG	8202/23T	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
YASMIN TABLET, FILM COATED 0.03MG/3MG	YASMIN TABLET, FILM COATED 0.03MG/3MG	1440/23T	BAYER HELLAS ABEE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
MAYMETSI TABLET, FILM COATED 50MG/850MG	MAYMETSI TABLET, FILM COATED 50MG/850MG	5499/23T	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
MAYMETSI TABLET, FILM COATED 50MG/1000MG	MAYMETSI TABLET, FILM COATED 50MG/1000MG	5500/23T	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
FLUOROURACIL ACCORD SOLUTION FOR INJECTION OR INFUSION 50MG/ML	FLUOROURACIL ACCORD SOLUTION FOR INJECTION OR INFUSION 50MG/ML	7830/23T	ACCORD HEALTHCARE S.L.U	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
INFANRIX TETRA SUSPENSION FOR INJECTION	INFANRIX TETRA SUSPENSION FOR INJECTION	2726/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e).2. z) Other variation
HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	2723/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation.
PRIORIX POWDER & SOLVENT	PRIORIX POWDER & SOLVENT	2725/23T	GLAXOSMITHKLINE	B.II.e).2. z) Other variation

FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE		BIOLOGICALS SA	
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	2728/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.e).2. z) Other variation
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5 ML	FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5 ML	2727/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.e).2. z) Other variation
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	2722/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.e.2.z-Change in the specification parameters and/or limits of the immediate packaging of the finished product-other variation
HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	2724/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation.
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	2729/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.e).2. z) Other variation
ISOREM TABLET, SUBLINGUAL 5MG	ISOREM TABLET, SUBLINGUAL 5MG	10322/23T, 10323/23T, 10324/23T, 10325/23T	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 - Eur B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.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
HALDOL ORAL SOLUTION 2MG/ML	HALDOL ORAL SOLUTION 2MG/ML	8213/23T	JANSSEN-CILAG INTERNATIONAL NV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
NAUTISOL TABLET 5MG	NAUTISOL TABLET 5MG	10292/23T	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
ALGOFEN DUOFAST TABLET	ALGOFEN DUOFAST TABLET	9301/23T	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
DYMISTA NASAL SPRAY, SUSPENSION	DYMISTA NASAL SPRAY, SUSPENSION	9257/23T	VIATRIS HEALTHCARE LIMITED.	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	8244/23T	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
PANADOL TABLET, FILM COATED 500MG	PANADOL TABLET, FILM COATED 500MG	10361/23T	HALEON HELLAS SINGLE MEMBER SOCIETE ANONYME (TRADING AS HALEON HELLAS)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BISOLOC TABLET, FILM COATED 5MG	BISOLOC TABLET, FILM COATED 5MG	10363/23T	SAPIENS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the

				manufacture of the finished product - Other changes
BISOLOC TABLET, FILM COATED 2.5MG	BISOLOC TABLET, FILM COATED 2.5MG	10364/23T	SAPIENS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
BISOLOC TABLET, FILM COATED 10MG	BISOLOC TABLET, FILM COATED 10MG	10362/23T	SAPIENS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
LOSAR TABLET, FILM COATED 50MG	LOSAR TABLET, FILM COATED 50MG	10259/23T	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
LOSAR TABLET, FILM COATED 100MG	LOSAR TABLET, FILM COATED 100MG	10258/23T	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
OMNIPAQUE SOLUTION FOR INJECTION 350MGI/ML	OMNIPAQUE SOLUTION FOR INJECTION 350MGI/ML	1208/23T, 1209/23T, 1210/23T, 1211/23T, 1212/23T	GE HEALTHCARE AS (NYDALEN)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OMNIPAQUE SOLUTION FOR INJECTION 350MGI/ML	OMNIPAQUE SOLUTION FOR INJECTION 350MGI/ML	1208/23T, 1209/23T, 1210/23T, 1211/23T, 1212/23T	GE HEALTHCARE AS (NYDALEN)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OMNIPAQUE SOLUTION FOR INJECTION 300MGI/ML	OMNIPAQUE SOLUTION FOR INJECTION 300MGI/ML	1213/23T, 1214/23T, 1215/23T, 1216/23T, 1217/23T	GE HEALTHCARE AS (NYDALEN)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
OMNIPAQUE SOLUTION FOR INJECTION 300MGI/ML	OMNIPAQUE SOLUTION FOR INJECTION 300MGI/ML	1213/23T, 1214/23T, 1215/23T, 1216/23T, 1217/23T	GE HEALTHCARE AS (NYDALEN)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package

				Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
MEDODEXAN SOLUTION FOR INJECTION OR INFUSION 4MG/ML	MEDODEXAN SOLUTION FOR INJECTION OR INFUSION 4MG/ML	10034/23T	MEDOCHEMIE LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
AMOXAPEN CAPSULE, HARD 250MG	AMOXAPEN CAPSULE, HARD 250MG	10027/23T	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)
AMOXAPEN CAPSULE, HARD 500MG	AMOXAPEN CAPSULE, HARD 500MG	10026/23T	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)
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/25MG	OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/25MG	1947/22T	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/12.5MG	OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/12.5MG	1944/22T	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/25MG	OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 20MG/25MG	1945/22T	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/12.5MG	OLMESARTAN/HYDROCHLOROTHIAZIDE TAD TABLET, FILM COATED 40MG/12.5MG	1946/22T	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
BROXIVAN TABLET 30MG	BROXIVAN TABLET 30MG	3756/23T	MEDOCHEMIE LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products

BROXIVAN TABLET 30MG	BROXIVAN TABLET 30MG	7594/23T	MEDOCHEMIE 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
TENORMIN TABLET, FILM COATED 25MG	TENORMIN TABLET, FILM COATED 25MG	9926/23T, 9927/23T, 9928/23T	ATNAHS PHARMA NETHERLAND S B.V.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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
TENORMIN TABLET, FILM COATED 100MG	TENORMIN TABLET, FILM COATED 100MG	9920/23T, 9921/23T, 9922/23T	ATNAHS PHARMA NETHERLAND S B.V.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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
TENORMIN TABLET, FILM COATED 50MG	TENORMIN TABLET, FILM COATED 50MG	9923/23T, 9924/23T, 9925/23T	ATNAHS PHARMA NETHERLAND S B.V.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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
TESTOGEL GEL 50MG	TESTOGEL GEL 50MG	9467/23T	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	TESTOGEL GEL 25MG	9468/23T	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
AZITHROMYCIN JUBILANT TABLET, FILM COATED 500MG	AZITHROMYCIN JUBILANT TABLET, FILM COATED 500MG	9790/23T	JUBILANT PHARMACEUTICALS NV	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
AZITHROMYCIN JUBILANT TABLET, FILM COATED 250MG	AZITHROMYCIN JUBILANT TABLET, FILM COATED 250MG	9791/23T	JUBILANT PHARMACEUTICALS NV	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
IBUTOMOL TABLET, FILM COATED 200MG/500MG	IBUTOMOL TABLET, FILM COATED 200MG/500MG	9118/23T, 9119/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For

				an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZESTRIL TABLET 5MG	ZESTRIL TABLET 5MG	10271/23T, 10272/23T	ATNAHS PHARMA NETHERLANDS B.V.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
ZESTRIL TABLET 20MG	ZESTRIL TABLET 20MG	10273/23T, 10274/23T	ATNAHS PHARMA NETHERLANDS B.V.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
ZESTRIL TABLET 10MG	ZESTRIL TABLET 10MG	10269/23T, 10270/23T	ATNAHS PHARMA NETHERLANDS B.V.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	7966/23T	BAXTER (HELLAS) EPE	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

ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 20MG	ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 20MG	737/23T	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
ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 40MG	736/23T	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
CLOZAPINE ACCORD TABLET 100MG	CLOZAPINE ACCORD TABLET 100MG	8678/23T	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
CLOZAPINE ACCORD TABLET 25MG	CLOZAPINE ACCORD TABLET 25MG	8679/23T	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
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5 ML	FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5 ML	8885/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
PRAGIOLA CAPSULE, HARD 25MG	PRAGIOLA CAPSULE, HARD 25MG	9175/23T	KRKA D.D. NOVO MESTO	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
PRAGIOLA CAPSULE, HARD 75MG	PRAGIOLA CAPSULE, HARD 75MG	9174/23T	KRKA D.D. NOVO MESTO	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
PRAGIOLA CAPSULE, HARD 300MG	PRAGIOLA CAPSULE, HARD 300MG	9172/23T	KRKA D.D. NOVO MESTO	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
PRAGIOLA CAPSULE, HARD 150MG	PRAGIOLA CAPSULE, HARD 150MG	9173/23T	KRKA D.D. NOVO MESTO	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
COSOPT IMULTI EYE DROPS, SOLUTION (20MG/5MG)/ML	COSOPT IMULTI EYE DROPS, SOLUTION (20MG/5MG)/ML	920/23T	VIANEX 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
COSOPT IMULTI EYE DROPS, SOLUTION (20MG/5MG)/ML	COSOPT IMULTI EYE DROPS, SOLUTION (20MG/5MG)/ML	2485/23T	VIANEX S.A	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
NAROX TABLET, FILM COATED 30MG	NAROX TABLET, FILM COATED 30MG	10263/23T	DELORBIS PHARMACEU TICALS 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)*
NAROX TABLET, FILM COATED 60MG	NAROX TABLET, FILM COATED 60MG	10262/23T	DELORBIS PHARMACEU TICALS 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)*
NAROX TABLET, FILM COATED 90MG	NAROX TABLET, FILM COATED 90MG	10261/23T	DELORBIS PHARMACEU TICALS 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)*
NAROX TABLET, FILM COATED 120MG	NAROX TABLET, FILM COATED 120MG	10260/23T	DELORBIS PHARMACEU TICALS 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)*
MILOREX TABLET 5MG/50MG	MILOREX TABLET 5MG/50MG	9906/23T, 9907/23T	REMEDICA LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF B.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
VELORIN TABLET, FILM COATED 50MG	VELORIN TABLET, FILM COATED 50MG	8352/23T, 8353/23T, 8354/23T	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 - 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)* 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
VELORIN TABLET, FILM COATED 25MG	VELORIN TABLET, FILM COATED 25MG	8355/23T, 8356/23T, 8357/23T	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 - 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)* 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
VELORIN TABLET, FILM COATED 100MG	VELORIN TABLET, FILM COATED 100MG	8358/23T, 8359/23T, 8360/23T	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 - 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)* 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
TEKCIS RADIONUCLIDE GENERATOR 2-50 GBq	TEKCIS RADIONUCLIDE GENERATOR 2-50 GBq	7683/23T	CIS BIO INTERNATIONAL	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
VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	8450/23T	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
LIPOCAT TABLET, FILM COATED 10MG/40MG	LIPOCAT TABLET, FILM COATED 10MG/40MG	5855/23T, 5856/23T, 5857/23T	ELPEN PHARMACEUTICAL CO INC	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
LIPOCAT TABLET, FILM COATED 10MG/80MG	LIPOCAT TABLET, FILM COATED 10MG/80MG	5852/23T, 5853/23T, 5854/23T	ELPEN PHARMACEUTICAL CO INC	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
LIPOCAT TABLET, FILM COATED 10MG/20MG	LIPOCAT TABLET, FILM COATED 10MG/20MG	5858/23T, 5859/23T, 5860/23T	ELPEN PHARMACEUTICAL CO INC	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
LIPOCAT TABLET, FILM COATED 10MG/10MG	LIPOCAT TABLET, FILM COATED 10MG/10MG	5861/23T, 5862/23T, 5863/23T	ELPEN PHARMACEUTICAL CO INC	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
PRILIGY TABLET, FILM COATED 30MG	PRILIGY TABLET, FILM COATED 30MG	8420/23T	MENARINI HELLAS S.A.	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PRILIGY TABLET, FILM COATED 60MG	PRILIGY TABLET, FILM COATED 60MG	8419/23T	MENARINI HELLAS S.A.	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
AFENTRAL TABLET, FILM COATED 20MG	AFENTRAL TABLET, FILM COATED 20MG	9145/23T	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
AFENTRAL TABLET, FILM COATED 30MG	AFENTRAL TABLET, FILM COATED 30MG	9144/23T	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
CANESTEN CUTANEOUS SOLUTION 1%	CANESTEN CUTANEOUS SOLUTION 1%	10143/23T	BAYER HELLAS ABEE	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
HYDROXYCHLOROQUINE SULFATE ACCORD TABLET, FILM COATED 200MG	HYDROXYCHLOROQUINE SULFATE ACCORD TABLET, FILM COATED 200MG	9502/23T	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
VALSARTAN JUBILANT TABLET, FILM COATED 80MG	VALSARTAN JUBILANT TABLET, FILM COATED 80MG	9707/23T, 9708/23T, 9709/23T, 9710/23T	JUBILANT PHARMACEUTICALS NV	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.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.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
VALSARTAN JUBILANT TABLET, FILM COATED 160MG	VALSARTAN JUBILANT TABLET, FILM COATED 160MG	9703/23T, 9704/23T, 9705/23T, 9706/23T	JUBILANT PHARMACEUTICALS NV	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.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.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
VALSARTAN JUBILANT TABLET, FILM COATED 40MG	VALSARTAN JUBILANT TABLET, FILM COATED 40MG	9711/23T, 9712/23T, 9713/23T, 9714/23T	JUBILANT PHARMACEUTICALS NV	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.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the B.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
HYDROXY CHLOROQ UINE SULFATE ACCORD TABLET, FILM COATED 200MG	HYDROXY CHLOROQ UINE SULFATE ACCORD TABLET, FILM COATED 200MG	6319/23T	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
SUTIREM CAPSULE, HARD 12.5MG	SUTIREM CAPSULE, HARD 12.5MG	10054/23T, 10055/23T	REMEDICA LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File 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 -
SUTIREM CAPSULE, HARD 25MG	SUTIREM CAPSULE, HARD 25MG	10052/23T, 10053/23T	REMEDICA LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File 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 -
SUTIREM CAPSULE, HARD 50MG	SUTIREM CAPSULE, HARD 50MG	10048/23T, 10049/23T	REMEDICA LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File 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 -
SUTIREM CAPSULE, HARD 37.5MG	SUTIREM CAPSULE, HARD 37.5MG	10050/23T, 10051/23T	REMEDICA LTD	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active

				substance - Minor change to the restricted part of an Active Substance Master File 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 -
HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	2718/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e.z - Change in container closure system of the Finished Product - Other variation
HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	2717/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e.z - Change in container closure system of the Finished Product - Other variation
ENGERIX-B PEDIATRIC SUSPENSION FOR INJECTION 10MCG/0.5 ML	ENGERIX-B PEDIATRIC SUSPENSION FOR INJECTION 10MCG/0.5 ML	2720/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e.z: Container closure system
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	2716/23T	GLAXOSMITHKLINE BIOLOGICALS SA	z) Other variation
ENGERIX-B SUSPENSION FOR INJECTION 20MCG/1ML	ENGERIX-B SUSPENSION FOR INJECTION 20MCG/1ML	2719/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e.z: Container closure system
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	2721/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e.z -Change in container closure system of the finished product- Other variation
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	2715/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e). z) Other variation
HAVRIX ADULTS	HAVRIX ADULTS	1195/23T	GLAXOSMITHKLINE	B.IV.1.c - Change of a measuring or administration device - Addition or

SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML		BIOLOGICALS SA	replacement of a device which is an integrated part of the primary packaging.
INFANRIX TETRA SUSPENSION FOR INJECTION	INFANRIX TETRA SUSPENSION FOR INJECTION	1193/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.IV.1.c). Addition or replacement of a device which is an integrated part of the primary packaging
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	1194/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.IV.1.c). Addition or replacement of a device which is an integrated part of the primary packaging
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	2768/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.d).2. d) Other changes to a test procedure (including replacement or addition)
HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	2764/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition).
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	2767/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.d).2. d) Other changes to a test procedure (including replacement or addition)
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	2766/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.d.2.d- Change in test procedure tor the finished product-Other changes to a test procedure (including replacemet of addition)
HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	2765/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition).
HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	4056/23T, 4057/23T, 4058/23T, 4059/23T, 4060/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.c).2. d) Other changes to a test procedure (including replacement or addition)
HAVRIX JUNIOR SUSPENSI	HAVRIX JUNIOR SUSPENSI	4051/23T, 4052/23T, 4053/23T, 4054/23T, 4055/23T	GLAXOSMITH KLINE	B.II.c).2. d) Other changes to a test procedure (including replacement or addition)

ON FOR INJECTION 720 ELISA UNIT/0.5ML	ON FOR INJECTION 720 ELISA UNIT/0.5ML		BIOLOGICALS SA	
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	4031/23T, 4032/23T, 4033/23T, 4034/23T, 4035/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.d).2. d) Other changes to a test procedure (including replacement or addition)
INFANRIX TETRA SUSPENSION FOR INJECTION	INFANRIX TETRA SUSPENSION FOR INJECTION	4036/23T, 4037/23T, 4038/23T, 4039/23T, 4040/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.d).2. d) Other changes to a test procedure (including replacement or addition)
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	1201/23T	SANOFI PASTEUR.	B.I.b.2.z) Update the qualification protocol already registered for the internal PRP-T reference standard batch used for
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	7490/22T	SANOFI PASTEUR.	Deletion of an in-process test (intradermal test) applied during
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	7489/22T	SANOFI PASTEUR.	the manufacture of the Purified Diphtheria Toxoid Drug Substance
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	2800/23T	SANOFI PASTEUR.	Change in the “Absence of toxin (specific toxicity) and
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	2801/23T	SANOFI PASTEUR.	irreversibility of toxoid” Test, i.e., removal of the “irreversibility of toxoid” part of the
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	7520/22T, 7521/22T	SANOFI PASTEUR.	test, with consequential change in the acceptance criteria, in line with the updated
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	7518/22T, 7519/22T	SANOFI PASTEUR.	Ph. Eur. product monograph 0452

AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	7656/23T	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
TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 200MG/VIAL	TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 200MG/VIAL	10237/23T	DEMO 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
TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 400MG/VIAL	TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 400MG/VIAL	10236/23T	DEMO 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
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	8817/23T, 8818/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)
PANTOPRAZOLE ACCORD POWDER FOR SOLUTION FOR INJECTION 40MG/VIAL	PANTOPRAZOLE ACCORD POWDER FOR SOLUTION FOR INJECTION 40MG/VIAL	9336/23T, 9337/23T	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material,

				reagent or excipient (when mentioned in the dossier)*
CISPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	CISPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	10113/23T	PFIZER HELLAS AE	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
EPIDUO GEL (0.001G/0.025G)G	EPIDUO GEL (0.001G/0.025G)G	6170/23T, 7726/23T	GALDERMA INTERNATIONAL,FRANCE	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF 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 -
EPIDUO FORTE GEL 0.3%/2.5%	EPIDUO FORTE GEL 0.3%/2.5%	6169/23T, 7725/23T	GALDERMA INTERNATIONAL,FRANCE	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF 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 -
REMABIRAT TABLET, FILM COATED 1000MG	REMABIRAT TABLET, FILM COATED 1000MG	10024/23T	REMEDICA LTD	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)
CHOLZET CAPSULE, HARD 20MG/10MG	CHOLZET CAPSULE, HARD 20MG/10MG	9335/22T, 9336/22T, 9337/22T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZERGYÁR ZRT)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND 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.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
CHOLZET CAPSULE, HARD 10MG/10MG	CHOLZET CAPSULE, HARD 10MG/10MG	9338/22T, 9339/22T, 9340/22T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP C.I.4 C.I.4 - SAFETY, EFFICACY,

			GYÓGYSZER GYÁR ZRT)	PHARMACOVIGILANCE CHANGES - HUMAN AND 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.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
CHOLZET CAPSULE, HARD 40MG/10MG	CHOLZET CAPSULE, HARD 40MG/10MG	9332/22T, 9333/22T, 9334/22T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND 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.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
CHOLZET CAPSULE, HARD 20MG/10MG	CHOLZET CAPSULE, HARD 20MG/10MG	3102/23T, 3103/23T, 3104/23T, 3105/23T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	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 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: A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code 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
CHOLZET CAPSULE, HARD 10MG/10MG	CHOLZET CAPSULE, HARD 10MG/10MG	3106/23T, 3107/23T, 3108/23T, 3109/23T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	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 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: A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code 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
CHOLZET CAPSULE, HARD 40MG/10MG	CHOLZET CAPSULE, HARD 40MG/10MG	3098/23T, 3099/23T, 3100/23T, 3101/23T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	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 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: A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code 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
VITIS VINIFERA STADA TABLET, FILM COATED 360MG	VITIS VINIFERA STADA TABLET, FILM COATED 360MG	8429/23T	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
CIFLOXACIN EAR DROPS SOLUTION 3MG/ML	CIFLOXACIN EAR DROPS SOLUTION 3MG/ML	10022/23T, 10023/23T	VERISFIELD 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

CANESTEN VAGINAL CREAM 2%	CANESTEN VAGINAL CREAM 2%	9956/23T, 9957/23T, 9958/23T, 9959/23T	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 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
LINEZID SOLUTION FOR INFUSION 2MG/ML	LINEZID SOLUTION FOR INFUSION 2MG/ML	9838/23T	SAPIENS PHARMACEUTICALS LTD	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
CONCERTA TABLET, PROLONGED-RELEASE 18MG	CONCERTA TABLET, PROLONGED-RELEASE 18MG	7982/23T, 7983/23T, 7984/23T	JANSSEN-CILAG INTERNATIONAL NV	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.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
CONCERTA TABLET, PROLONGED-RELEASE 36MG	CONCERTA TABLET, PROLONGED-RELEASE 36MG	7979/23T, 7980/23T, 7981/23T	JANSSEN-CILAG INTERNATIONAL NV	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.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
CONCERTA TABLET, PROLONGED-RELEASE 54MG	CONCERTA TABLET, PROLONGED-RELEASE 54MG	7976/23T, 7977/23T, 7978/23T	JANSSEN-CILAG INTERNATIONAL NV	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.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
CONCERTA TABLET, PROLONGED-RELEASE 36MG	CONCERTA TABLET, PROLONGED-RELEASE 36MG	157/23T	JANSSEN-CILAG INTERNATIONAL NV	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*
CONCERTA TABLET, PROLONGED-RELEASE 18MG	CONCERTA TABLET, PROLONGED-RELEASE 18MG	158/23T	JANSSEN-CILAG INTERNATIONAL NV	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*
CONCERTA TABLET, PROLONGED-RELEASE 54MG	CONCERTA TABLET, PROLONGED-RELEASE 54MG	156/23T	JANSSEN-CILAG INTERNATIONAL NV	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*
VITIS VINIFERA STADA TABLET, FILM COATED 360MG	VITIS VINIFERA STADA TABLET, FILM COATED 360MG	8441/23T	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MEDOTRAMOL TABLET, FILM COATED 37.5MG/325MG	MEDOTRAMOL TABLET, FILM COATED 37.5MG/325MG	10039/23T	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

TAZOREX POWDER FOR SOLUTION FOR INJECTION (4G/0.5G)/VIAL	TAZOREX POWDER FOR SOLUTION FOR INJECTION (4G/0.5G)/VIAL	10088/23T	DEMO 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
TAZOREX POWDER FOR SOLUTION FOR INJECTION (4G/0.5G)/VIAL	TAZOREX POWDER FOR SOLUTION FOR INJECTION (4G/0.5G)/VIAL	10036/23T	DEMO 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
MICAFUNGIN/PHARMAZAC POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG	MICAFUNGIN/PHARMAZAC POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 100MG	7677/23T	PHARMAZAC S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
MICAFUNGIN/PHARMAZAC POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 50MG	MICAFUNGIN/PHARMAZAC POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 50MG	7678/23T	PHARMAZAC S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
CIPROXIN TABLET, FILM COATED 500MG	CIPROXIN TABLET, FILM COATED 500MG	2288/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
YASMIN TABLET, FILM COATED 0.03MG/3MG	YASMIN TABLET, FILM COATED 0.03MG/3MG	2287/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AVELOX TABLET, FILM COATED 400MG	AVELOX TABLET, FILM COATED 400MG	2289/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

YASMINELLE TABLET, FILM COATED 0.02MG/3MG	YASMINELLE TABLET, FILM COATED 0.02MG/3MG	2286/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AVELOX SOLUTION FOR INFUSION 400MG/250ML	AVELOX SOLUTION FOR INFUSION 400MG/250ML	2290/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOVIST PFS SOLUTION FOR INJECTION IN PREFILLED SYRINGE 1MMOL/ML	GADOVIST PFS SOLUTION FOR INJECTION IN PREFILLED SYRINGE 1MMOL/ML	2292/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	2293/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ASPIRIN EXPRESS TABLET, COATED 500MG	ASPIRIN EXPRESS TABLET, COATED 500MG	2282/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
QLAIRA TABLET, FILM COATED	QLAIRA TABLET, FILM COATED	2285/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GYNO-CANESTEN VAGINAL CAPSULE, SOFT 500MG	GYNO-CANESTEN VAGINAL CAPSULE, SOFT 500MG	2283/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PRIMOVIST SOLUTION FOR INJECTION IN PREFILLED SYRINGE 0.25MMOL/ML	PRIMOVIST SOLUTION FOR INJECTION IN PREFILLED SYRINGE 0.25MMOL/ML	2294/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG(4000 IU)/0.4ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG(4000 IU)/0.4ML	8545/23T	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 SYRINGE 60MG(6000 IU)/0.6ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 60MG(6000 IU)/0.6ML	8544/23T	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 SYRINGE 20MG(2000 IU)/0.2ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG(2000 IU)/0.2ML	8546/23T	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 SYRINGE 80MG(8000 IU)/0.8ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 80MG(8000 IU)/0.8ML	8543/23T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GEMCITABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	GEMCITABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	5431/23T	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
TICAGRELOR/MYLAN TABLET, FILM COATED 90MG	TICAGRELOR/MYLAN TABLET, FILM COATED 90MG	5005/23T	MYLAN IRELAND LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
TICAGRELOR/MYLAN TABLET, FILM COATED 60MG	TICAGRELOR/MYLAN TABLET, FILM COATED 60MG	5006/23T	MYLAN IRELAND LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
CABAZITAXEL FRESENIUS KABI CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	CABAZITAXEL FRESENIUS KABI CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	5093/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
MELOX TABLET 15MG	MELOX TABLET 15MG	10037/23T	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
MELOX TABLET 7.5MG	MELOX TABLET 7.5MG	10038/23T	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
THYROFIX TABLET 88MCG	THYROFIX TABLET 88MCG	8779/23T, 8780/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 175MCG	THYROFIX TABLET 175MCG	8767/23T, 8768/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 150MCG	THYROFIX TABLET 150MCG	8769/23T, 8770/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 200MCG	THYROFIX TABLET 200MCG	8765/23T, 8766/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 75MCG	THYROFIX TABLET 75MCG	8781/23T, 8782/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

				Updated certificate from an already approved manufacturer
THYROFIX TABLET 50MCG	THYROFIX TABLET 50MCG	8785/23T, 8786/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 112MCG	THYROFIX TABLET 112MCG	8775/23T, 8776/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 25MCG	THYROFIX TABLET 25MCG	8787/23T, 8788/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 62MCG	THYROFIX TABLET 62MCG	8783/23T, 8784/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 125MCG	THYROFIX TABLET 125MCG	8773/23T, 8774/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 100MCG	THYROFIX TABLET 100MCG	8777/23T, 8778/23T	UNI-PHARMA KLEON TSETIS	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

			PHARMACEUTICAL LABORATORIES SA	Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 137MCG	THYROFIX TABLET 137MCG	8771/23T, 8772/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
THYROFIX TABLET 13MCG	THYROFIX TABLET 13MCG	8789/23T, 8790/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
HALDOL DECANOAS INJECTION 50MG/1ML	HALDOL DECANOAS INJECTION 50MG/1ML	8212/23T	JANSSEN-CILAG INTERNATIONAL NV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
HALDOL DECANOAS INJECTION 100MG/1ML	HALDOL DECANOAS INJECTION 100MG/1ML	8211/23T	JANSSEN-CILAG INTERNATIONAL NV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	5021/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	4954/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	5022/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	4969/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DICETEL TABLET, FILM	DICETEL TABLET, FILM	1412/23T	VIATRIS HEALTHCARE LIMITED.	B.I.z B.I.z - Quality change - Active substance - Other variation

COATED 50MG	COATED 50MG			
GENEMENT TABLET, FILM COATED 20MG	GENEMENT TABLET, FILM COATED 20MG	8560/23T	SAPIENS 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
GENEMENT TABLET, FILM COATED 5MG	GENEMENT TABLET, FILM COATED 5MG	8561/23T	SAPIENS 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
CEFEPIME APTAPHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	CEFEPIME APTAPHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	8971/23T	APTA MEDICA INTERNACIONAL D.O.O.	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
CEFEPIME APTAPHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G	CEFEPIME APTAPHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G	8970/23T	APTA MEDICA INTERNACIONAL D.O.O.	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
EPLERENONE ACCORD TABLET, FILM COATED 25MG	EPLERENONE ACCORD TABLET, FILM COATED 25MG	9881/23T, 9882/23T, 9883/23T	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

EPLERENONE ACCORD TABLET, FILM COATED 50MG	EPLERENONE ACCORD TABLET, FILM COATED 50MG	9878/23T, 9879/23T, 9880/23T	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
MEDAXONUM LIDO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1G/VIAL	MEDAXONUM LIDO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1G/VIAL	10032/23T	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
MEDAXONUM LIDO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500MG/VIAL	MEDAXONUM LIDO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500MG/VIAL	10033/23T	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
BETAC TABLET, FILM COATED 20MG	BETAC TABLET, FILM COATED 20MG	6844/23T, 6845/23T, 6846/23T, 6847/23T	MEDOCHEMIE LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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.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
ATORVASTATIN GENERICS	ATORVASTATIN GENERICS	9056/23T	GENERICS PHARMA	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size

TABLET, FILM COATED 40MG	TABLET, FILM COATED 40MG		HELLAS LIMITED	(including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
STOVADIS TABLET, FILM COATED 12.5MG/7.5 MG	STOVADIS TABLET, FILM COATED 12.5MG/7.5 MG	8898/23T	LES LABORATOIR ES SERVIER	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
STOVADIS TABLET, FILM COATED 25MG/7.5M G	STOVADIS TABLET, FILM COATED 25MG/7.5M G	8900/23T	LES LABORATOIR ES SERVIER	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
STOVADIS TABLET, FILM COATED 6.25MG/5M G	STOVADIS TABLET, FILM COATED 6.25MG/5M G	8901/23T	LES LABORATOIR ES SERVIER	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
STOVADIS TABLET, FILM COATED 25MG/5MG	STOVADIS TABLET, FILM COATED 25MG/5MG	8899/23T	LES LABORATOIR ES SERVIER	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
STOVADIS TABLET, FILM COATED 6.25MG/7.5 MG	STOVADIS TABLET, FILM COATED 6.25MG/7.5 MG	8896/23T	LES LABORATOIR ES SERVIER	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
STOVADIS TABLET, FILM COATED 12.5MG/5M G	STOVADIS TABLET, FILM COATED 12.5MG/5M G	8897/23T	LES LABORATOIR ES SERVIER	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
MICROLAX RECTAL SOLUTION (0.45G/0.06 45G/4.465G)/DOSE	MICROLAX RECTAL SOLUTION (0.45G/0.06 45G/4.465G)/DOSE	9102/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SUBUTEX TABLET, SUBLINGU AL 0.4MG	SUBUTEX TABLET, SUBLINGU AL 0.4MG	9702/23T	INDIVIOR EUROPE 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.
SUBUTEX TABLET, SUBLINGUAL 2MG	SUBUTEX TABLET, SUBLINGUAL 2MG	9701/23T	INDIVIOR EUROPE 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.
SUBUTEX TABLET, SUBLINGUAL 8MG	SUBUTEX TABLET, SUBLINGUAL 8MG	9700/23T	INDIVIOR EUROPE 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.
BETAC TABLET, FILM COATED 10MG	BETAC TABLET, FILM COATED 10MG	6848/23T, 6849/23T, 6850/23T, 6851/23T	MEDOCHEMIE LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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.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
BIORPHEN SOLUTION FOR INJECTION OR INFUSION 0.1MG/ML	BIORPHEN SOLUTION FOR INJECTION OR INFUSION 0.1MG/ML	8791/23T, 8792/23T, 8793/23T, 8794/23T, 8795/23T, 8796/23T	SINTETICA GMBH	B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product -

				Deletion of a non-significant in-process test B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.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
CLOMIPRAMINE TABLET, FILM COATED 25MG	CLOMIPRAMINE TABLET, FILM COATED 25MG	9496/23T, 9497/23T, 9498/23T	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
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 50MG/ML	INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 50MG/ML	4711/23T	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
REXANIB TABLET, FILM COATED 200MG	REXANIB TABLET, FILM COATED 200MG	6331/23T	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)
TAMSULOSIN AUROBINDO TABLET, PROLONGED-RELEASE 0.4MG	TAMSULOSIN AUROBINDO TABLET, PROLONGED-RELEASE 0.4MG	6893/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	6404/23T	TEVA PHARMA BV	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing

PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	6402/23T	TEVA PHARMA BV	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	6403/23T	TEVA PHARMA BV	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
RAPIBLOC POWDER FOR SOLUTION FOR INFUSION 300MG/VIAL	RAPIBLOC POWDER FOR SOLUTION FOR INFUSION 300MG/VIAL	8381/23T	AMOMED PHARMA 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
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (2G/0.25G)/VIAL	PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (2G/0.25G)/VIAL	9054/23T	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (4G/0.5G)/VIAL	PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (4G/0.5G)/VIAL	9053/23T	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
IMODIUM PLUS TABLET 2MG/125MG	IMODIUM PLUS TABLET 2MG/125MG	8176/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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
CANDESARTAN TAD TABLET 16MG	CANDESARTAN TAD TABLET 16MG	8946/23T	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	CANDESARTAN TAD TABLET 32MG	8945/23T	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
FENIVIR TINTED CREAM 1%	FENIVIR TINTED CREAM 1%	1246/23T, 1247/23T, 1248/23T, 1249/23T, 1250/23T, 1251/23T, 1252/23T, 1253/23T, 1254/23T, 1255/23T, 1256/23T, 1257/23T, 1258/23T, 1259/23T, 1260/23T, 1261/23T, 1262/23T, 1263/23T, 1264/23T, 1265/23T, 1266/23T, 1267/23T, 1268/23T, 1269/23T	OMEGA PHARMA HELLAS S.A	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits 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 th 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 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 B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or star B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions o B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediat
LIPOFOR CAPSULE, HARD 300MG	LIPOFOR CAPSULE, HARD 300MG	8887/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LIPOFOR TABLET, FILM COATED 600MG	LIPOFOR TABLET, FILM COATED 600MG	8886/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
REFENTA POWDER FOR CONCENTRATE FOR SOLUTION	REFENTA POWDER FOR CONCENTRATE FOR SOLUTION	9949/23T	SAPIENS PHARMACEUTICALS LTD	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

FOR INJECTION OR INFUSION 2MG	FOR INJECTION OR INFUSION 2MG			
REFENTA POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION 1MG	REFENTA POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION 1MG	9950/23T	SAPIENS PHARMACEUTICALS LTD	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
PRODUOD OPA SOLUTION FOR INFUSION (240MG+12 MG)/ML	PRODUOD OPA SOLUTION FOR INFUSION (240MG+12 MG)/ML	2153/23T, 2154/23T, 2155/23T, 2156/23T, 2157/23T	ABBVIE PHARMACEUTICALS S.A.	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data 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
BINOSTO EFFERVESCENT TABLET 70MG	BINOSTO EFFERVESCENT TABLET 70MG	8323/23T	GALENICA SA	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
ADAGREL TABLET, FILM COATED 75MG	ADAGREL TABLET, FILM COATED 75MG	8555/23T	SAPIENS PHARMACEUTICALS 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
PRISMASOL POTASSIUM SOLUTION FOR	PRISMASOL POTASSIUM SOLUTION FOR	7965/23T	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

HAEMOFILTRATION AND HAEMODIALYSIS 2MMOL/L	HAEMOFILTRATION AND HAEMODIALYSIS 2MMOL/L			material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 4MMOL/L	PRISMASOL POTASSIUM SOLUTION FOR HAEMOFILTRATION AND HAEMODIALYSIS 4MMOL/L	7964/23T	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
ROPIVACAINE KABI SOLUTION FOR INJECTION 5MG/ML	ROPIVACAINE KABI SOLUTION FOR INJECTION 5MG/ML	8005/23T	FRESENIUS KABI HELLAS A.E.	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 -
ROPIVACAINE KABI SOLUTION FOR INFUSION 2MG/ML	ROPIVACAINE KABI SOLUTION FOR INFUSION 2MG/ML	8006/23T	FRESENIUS KABI HELLAS A.E.	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 -
ROPIVACAINE KABI SOLUTION FOR INJECTION 2MG/ML	ROPIVACAINE KABI SOLUTION FOR INJECTION 2MG/ML	8007/23T	FRESENIUS KABI HELLAS A.E.	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 -
ROPIVACAINE KABI SOLUTION FOR INJECTION 7.5MG/ML	ROPIVACAINE KABI SOLUTION FOR INJECTION 7.5MG/ML	8004/23T	FRESENIUS KABI HELLAS A.E.	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 -
ROPIVACAINE KABI SOLUTION FOR INJECTION 10MG/ML	ROPIVACAINE KABI SOLUTION FOR INJECTION 10MG/ML	8003/23T	FRESENIUS KABI HELLAS A.E.	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 -
NEURONTIN CAPSULE, HARD 300MG	NEURONTIN CAPSULE, HARD 300MG	8130/23T, 8131/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a

				supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
ZOLOFT TABLET, FILM COATED 100MG	ZOLOFT TABLET, FILM COATED 100MG	8146/23T, 8147/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
CELEBREX CAPSULE, HARD 200MG	CELEBREX CAPSULE, HARD 200MG	8150/23T, 8151/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
CELEBREX CAPSULE, HARD 200MG	CELEBREX CAPSULE, HARD 200MG	8150/23T, 8151/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting

				material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
DETRUSITOL TABLET, FILM COATED 2MG	DETRUSITOL TABLET, FILM COATED 2MG	8122/23T, 8123/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
ZARATOR TABLET, FILM COATED 10MG	ZARATOR TABLET, FILM COATED 10MG	8138/23T, 8139/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
LIPITOR TABLET, FILM COATED 10MG	LIPITOR TABLET, FILM COATED 10MG	8140/23T, 8141/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used

				in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
LIPITOR TABLET, FILM COATED 20MG	LIPITOR TABLET, FILM COATED 20MG	8142/23T, 8143/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
INSPRA TABLET, FILM COATED 25MG	INSPRA TABLET, FILM COATED 25MG	8126/23T, 8127/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
NEURONTIN CAPSULE, HARD 400MG	NEURONTIN CAPSULE, HARD 400MG	8128/23T, 8129/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active

				substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
ZOLOFT TABLET, FILM COATED 50MG	ZOLOFT TABLET, FILM COATED 50MG	8148/23T, 8149/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
XALATAN EYE DROPS, SOLUTION 50MCG/ML	XALATAN EYE DROPS, SOLUTION 50MCG/ML	8132/23T, 8133/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
CELEBREX CAPSULE, HARD 100MG	CELEBREX CAPSULE, HARD 100MG	8152/23T, 8153/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the

				technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
CELEBREX CAPSULE, HARD 100MG	CELEBREX CAPSULE, HARD 100MG	8152/23T, 8153/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
LIPITOR TABLET, FILM COATED 40MG	LIPITOR TABLET, FILM COATED 40MG	8144/23T, 8145/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
INSPRA TABLET, FILM COATED 50MG	INSPRA TABLET, FILM COATED 50MG	8124/23T, 8125/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur.

				Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
ZARATOR TABLET, FILM COATED 20MG	ZARATOR TABLET, FILM COATED 20MG	8136/23T, 8137/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
ZARATOR TABLET, FILM COATED 40MG	ZARATOR TABLET, FILM COATED 40MG	8134/23T, 8135/23T	VIATRIS HELLAS LTD	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) 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
CELEBREX CAPSULE, HARD 200MG	CELEBREX CAPSULE, HARD 200MG	4155/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NORVASC CAPSULE, HARD 10MG	NORVASC CAPSULE, HARD 10MG	4158/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EFEXOR XR PROLONG	EFEXOR XR PROLONG	4166/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name

ED RELEASE CAPSULES 37.5MG	ED RELEASE CAPSULES 37.5MG			and/or address of the marketing authorisation holder
LIPITOR TABLET, CHEWABLE 5MG	LIPITOR TABLET, CHEWABLE 5MG	4174/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, CHEWABLE 20MG	LIPITOR TABLET, CHEWABLE 20MG	4172/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CELEBREX CAPSULE, HARD 100MG	CELEBREX CAPSULE, HARD 100MG	4156/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEURONTIN CAPSULE, HARD 300MG	NEURONTIN CAPSULE, HARD 300MG	4163/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
XALATAN EYE DROPS, SOLUTION 50MCG/ML	XALATAN EYE DROPS, SOLUTION 50MCG/ML	4167/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DETRUSITOL TABLET, FILM COATED 2MG	DETRUSITOL TABLET, FILM COATED 2MG	4157/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	4164/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NORVASC CAPSULE, HARD 5MG	NORVASC CAPSULE, HARD 5MG	4159/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZOLOFT TABLET, FILM COATED 100MG	ZOLOFT TABLET, FILM COATED 100MG	4178/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZARATOR TABLET, FILM COATED 20MG	ZARATOR TABLET, FILM COATED 20MG	4169/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, CHEWABLE 10MG	LIPITOR TABLET, CHEWABLE 10MG	4173/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZARATOR TABLET, FILM COATED 40MG	ZARATOR TABLET, FILM COATED 40MG	4170/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, CHEWABLE 40MG	LIPITOR TABLET, CHEWABLE 40MG	4171/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EFEXOR XR CAPSULE,	EFEXOR XR CAPSULE,	4165/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name

HARD, PROLONGED-RELEASE 75MG	HARD, PROLONGED-RELEASE 75MG			and/or address of the marketing authorisation holder
ZOLOFT TABLET, FILM COATED 50MG	ZOLOFT TABLET, FILM COATED 50MG	4179/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NEURONTIN CAPSULE, HARD 400MG	NEURONTIN CAPSULE, HARD 400MG	4162/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INSPRA TABLET, FILM COATED 25MG	INSPRA TABLET, FILM COATED 25MG	4161/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZARATOR TABLET, FILM COATED 10MG	ZARATOR TABLET, FILM COATED 10MG	4168/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INSPRA TABLET, FILM COATED 50MG	INSPRA TABLET, FILM COATED 50MG	4160/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, FILM COATED 10MG	LIPITOR TABLET, FILM COATED 10MG	4177/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, FILM COATED 40MG	LIPITOR TABLET, FILM COATED 40MG	4175/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LIPITOR TABLET, FILM COATED 20MG	LIPITOR TABLET, FILM COATED 20MG	4176/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DUODOPA INTESTINAL GEL	DUODOPA INTESTINAL GEL	7409/23T	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 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
ARICEPT TABLET, FILM COATED 5MG	ARICEPT TABLET, FILM COATED 5MG	9893/23T, 9894/23T, 9895/23T, 9896/23T	PFIZER HELLAS AE	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.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
ARICEPT TABLET, FILM COATED 10MG	ARICEPT TABLET, FILM COATED 10MG	9889/23T, 9890/23T, 9891/23T, 9892/23T	PFIZER HELLAS AE	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.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
HYDROCORTISONE MEDO POWDER FOR SOLUTION FOR INJECTION /INFUSION 100MG/VIAL	HYDROCORTISONE MEDO POWDER FOR SOLUTION FOR INJECTION /INFUSION 100MG/VIAL	9248/23T, 9249/23T	MEDOCHEMIE LTD	B.II.e.4.c B.II.e.4.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.6.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
ULCEDINE FILM COATED TABLETS 40MG	ULCEDINE FILM COATED TABLETS 40MG	7842/23T	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
ULCEDINE FILM COATED TABLETS 20mg	ULCEDINE FILM COATED TABLETS 20mg	7843/23T	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
ALZEDEM TABLET, FILM COATED 20MG	ALZEDEM TABLET, FILM COATED 20MG	9416/23T, 9417/23T, 9418/23T, 9419/23T, 9420/23T, 9421/23T	CODAL-SYNTO LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ALZEDEM TABLET, FILM COATED 5MG	ALZEDEM TABLET, FILM COATED 5MG	9434/23T, 9435/23T, 9436/23T, 9437/23T, 9438/23T, 9439/23T	CODAL-SYNTO LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ALZEDEM TABLET, FILM COATED 15MG	ALZEDEM TABLET, FILM COATED 15MG	9422/23T, 9423/23T, 9424/23T, 9425/23T, 9426/23T, 9427/23T	CODAL-SYNTO LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ALZEDEM TABLET, FILM COATED 10MG	ALZEDEM TABLET, FILM COATED 10MG	9428/23T, 9429/23T, 9430/23T, 9431/23T, 9432/23T, 9433/23T	CODAL-SYNTO LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
GAVISCON LIQUID SACHETS	GAVISCON LIQUID SACHETS	8688/23T, 8689/23T	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)
SEDISTRESS SLEEP TABLET, FILM COATED 500MG	SEDISTRESS SLEEP TABLET, FILM COATED 500MG	5810/23T	TILMAN S.A.	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is

				part of the approved dossier - Re-test period/storage period -
ALLUZIENCE SOLUTION FOR INJECTION 200 SPEYWOOD UNITS/ML	ALLUZIENCE SOLUTION FOR INJECTION 200 SPEYWOOD UNITS/ML	7690/23T	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
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	8351/23T	BIOTEST PHARMA GMBH	B.II.b.4.f B.II.b.4.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line)
KORANDIL TABLET 10MG	KORANDIL TABLET 10MG	9852/23T	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
KORANDIL TABLET 5MG	KORANDIL TABLET 5MG	9853/23T	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
KORANDIL TABLET 20MG	KORANDIL TABLET 20MG	9851/23T	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
LONATA EYE DROPS, SOLUTION (50MCG/5MG)/ML	LONATA EYE DROPS, SOLUTION (50MCG/5MG)/ML	6867/23T	PHARMATHEN S.A.	B.II.e.1.z B.II.e.1.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Other changes
HEXAFLU DAY & NIGHT	HEXAFLU DAY & NIGHT	5133/23T	JOHNSON & JOHNSON HELLAS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

TABLET 500MG/60MG AND 500MG/25MG	TABLET 500MG/60MG AND 500MG/25MG		CONSUMER AE	MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
NOPRILAM 500 TABLET, FILM COATED (500MG/125MG)	NOPRILAM 500 TABLET, FILM COATED (500MG/125MG)	9667/23T, 9668/23T, 9669/23T	BIAL-PORTELA & CA, SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	7767/23T	BIOTEST PHARMA GMBH	B.II.h.z B.II.h.z - QUALITY CHANGES - FINISHED PRODUCT - Adventitious Agents Safety - Other variation
CISATRACURIUM ACCORDPHARMA SOLUTION FOR INJECTION OR INFUSION 2MG/ML	CISATRACURIUM ACCORDPHARMA SOLUTION FOR INJECTION OR INFUSION 2MG/ML	8804/23T	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
AMICOR TABLET, FILM COATED 10MG	AMICOR TABLET, FILM COATED 10MG	3035/23T	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
AMICOR TABLET, FILM COATED 40MG	AMICOR TABLET, FILM COATED 40MG	3033/23T	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
AMICOR TABLET, FILM COATED 20MG	AMICOR TABLET, FILM COATED 20MG	3034/23T	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
PULMICORT TURBUHAL	PULMICORT TURBUHAL	9028/23T, 9029/23T	ASTRAZENECA AB	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer

ER POWDER FOR INHALATION 200MCG/DOSE	ER POWDER FOR INHALATION 200MCG/DOSE			(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.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
PULMICORT TURBUHALER POWDER FOR INHALATION 100MCG/DOSE	PULMICORT TURBUHALER POWDER FOR INHALATION 100MCG/DOSE	9030/23T, 9031/23T	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 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.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
METRONIDAZOLE VIOSER SOLUTION FOR INFUSION 500MG/100ML	METRONIDAZOLE VIOSER SOLUTION FOR INFUSION 500MG/100ML	8539/23T	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	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)
PULMOZYME NEBULISER SOLUTION 2500U/2.5ML	PULMOZYME NEBULISER SOLUTION 2500U/2.5ML	3195/23T, 3196/23T, 3197/23T, 3198/23T, 3199/23T	ROCHE (HELLAS) SA	B.II.b.2.b B.II.b.2.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method 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
GRAFALON CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	GRAFALON CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	7489/23T	NEOVII BIOTECH GMBH	B.II.g.2 B.II.g.2 - QUALITY CHANGES - FINISHED PRODUCT - Design Space and post approval change management protocol - Introduction of a post approval change management protocol related to the finished product
CERNEVIT POWDER FOR SOLUTION FOR INJECTION	CERNEVIT POWDER FOR SOLUTION FOR INJECTION	3459/23T, 3460/23T, 3461/23T	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
PULMOZYME NEBULISER SOLUTION 2500U/2.5ML	PULMOZYME NEBULISER SOLUTION 2500U/2.5ML	2752/23T, 2753/23T	ROCHE (HELLAS) SA	B.I.a.1.j B.I.a.1.j - 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 B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C
TANAFRA EYE DROPS, SOLUTION 50MCG/ML	TANAFRA EYE DROPS, SOLUTION 50MCG/ML	6755/23T	PHARMATHEN S.A.	B.II.e.1.z B.II.e.1.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Other changes
MILOREX TABLET 5MG/50MG	MILOREX TABLET 5MG/50MG	9827/23T	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
DIOVAN TABLET, FILM COATED 160MG	DIOVAN TABLET, FILM COATED 160MG	8337/23T	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)*
DIOVAN TABLET, FILM	DIOVAN TABLET, FILM	8338/23T	NOVARTIS IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance,

COATED 80MG	COATED 80MG			intermediate or finished product, packaging site, manufacturer 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 TABLET, FILM COATED 40MG	DIOVAN TABLET, FILM COATED 40MG	8339/23T	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)*
GLYCERYL TRINITRATE STERILE CONCENTRATE 5MG/ML	GLYCERYL TRINITRATE STERILE CONCENTRATE 5MG/ML	9469/23T	PFIZER HELLAS AE	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 100U	BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 100U	8906/23T, 8907/23T	MERZ PHARMACEUTICALS GMBH	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.4.f B.II.b.4.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line)
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 50U	BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 50U	8908/23T, 8909/23T	MERZ PHARMACEUTICALS GMBH	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.4.f B.II.b.4.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line)
CLINIMIX N14G30E SOLUTION	CLINIMIX N14G30E SOLUTION	9690/23T, 9691/23T	BAXTER (HELLAS) EPE	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion

FOR INFUSION	FOR INFUSION			of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used 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 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)
REMEVIA TABLET, FILM COATED 50MG	REMEVIA TABLET, FILM COATED 50MG	9381/23T, 9382/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size 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
REMEVIA TABLET, FILM COATED 100MG	REMEVIA TABLET, FILM COATED 100MG	9379/23T, 9380/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size 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
REMEVIA TABLET, FILM COATED 25MG	REMEVIA TABLET, FILM COATED 25MG	9383/23T, 9384/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size 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
ABIRATERONE PHARMASCIENCE TABLET, FILM COATED 500MG	ABIRATERONE PHARMASCIENCE TABLET, FILM COATED 500MG	4142/23T	PHARMASCIENCE INTERNATIONAL 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)
SPIRIVA INHALATION POWDER, HARD CAPSULE 18MCG	SPIRIVA INHALATION POWDER, HARD CAPSULE 18MCG	6749/23T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	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
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	OCTAGAM SOLUTION FOR INFUSION 50MG/ML	5937/23T	OCTAPHARMA (IP) SPRL	B.I.a.3.c B.I.a.3.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The change requires assessment of the comparability of a biological/immunological active substance
ONDANSETRON ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	ONDANSETRON ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	6412/23T, 6413/23T	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
BENDAMUSTINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	BENDAMUSTINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	3291/23T, 3292/23T	ACCORD HEALTHCARE S.L.U	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
NAVIREL CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	NAVIREL CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	7600/23T	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 40MG	PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 40MG	6261/23T, 6262/23T, 6263/23T, 6264/23T	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.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.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
PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 20MG	PANTOPRAZOLE TAD TABLET, GASTRO-RESISTANT 20MG	6265/23T, 6266/23T, 6267/23T, 6268/23T	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.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.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
SINECOD SYRUP 0.15%	SINECOD SYRUP 0.15%	8942/23T	HALEON HELLAS SINGLE MEMBER SOCIETE ANONYME (TRADING AS HALEON HELLAS)	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
PULMICORT TURBUHALER POWDER FOR INHALATIO	PULMICORT TURBUHALER POWDER FOR INHALATIO	9659/23T, 9660/23T, 9661/23T	ASTRAZENECA 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

N 200MCG/DOSE	N 200MCG/DOSE			the manufacturing process of 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 TURBUHALER POWDER FOR INHALATION 100MCG/DOSE	PULMICORT TURBUHALER POWDER FOR INHALATION 100MCG/DOSE	9662/23T, 9663/23T, 9664/23T	ASTRAZENECA 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
TRISEQUENS TABLET, FILM COATED	TRISEQUENS TABLET, FILM COATED	9284/23T	NOVO NORDISK HELLAS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority.
CANESTEN VAGINAL CREAM 2%	CANESTEN VAGINAL CREAM 2%	8978/23T, 8979/23T, 8980/23T, 8981/23T, 8982/23T, 8983/23T, 8984/23T, 8985/23T, 8986/23T, 8987/23T, 8988/23T, 8989/23T, 8990/23T, 8991/23T, 8992/23T, 8993/23T, 8994/23T, 8995/23T, 8996/23T, 8997/23T, 8998/23T, 8999/23T, 9000/23T	BAYER HELLAS ABEE	B.I.a.1.i B.I.a.1.i - QUALITY CHANGES - ACTIVE SUBSTANC B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANC B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANC B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBS B.I.d.1.b.3 B.I.d.1.b.3 - QUALITY CHANGES - ACTIVE SUBS B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PROD B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PROD B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PROD B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PROD B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PROD B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PROD B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PROD B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PROD B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PROD B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PROD B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PROD B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PROD
TRIATEC TABLET 2.5MG	TRIATEC TABLET 2.5MG	8739/23T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name

				and/or address of the marketing authorisation holder
TRIATEC TABLET 5MG	TRIATEC TABLET 5MG	8738/23T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
RIVAROLTO TABLET, FILM COATED 2.5MG	RIVAROLTO TABLET, FILM COATED 2.5MG	7673/23T	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)
RIVAROLTO TABLET, FILM COATED 10MG	RIVAROLTO TABLET, FILM COATED 10MG	7676/23T	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)
RIVAROLTO TABLET, FILM COATED 15MG	RIVAROLTO TABLET, FILM COATED 15MG	7675/23T	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)
RIVAROLTO TABLET, FILM COATED 20MG	RIVAROLTO TABLET, FILM COATED 20MG	7674/23T	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)
VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	9055/23T	PFIZER HELLAS AE	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
RAMI-AMLO CAPSULE, HARD (2.5+5)MG	RAMI-AMLO CAPSULE, HARD (2.5+5)MG	2121/23T, 2278/23T	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
RAMI-AMLO CAPSULE, HARD (5+10)MG	RAMI-AMLO CAPSULE, HARD (5+10)MG	2119/23T, 2276/23T	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
RAMI-AMLO CAPSULE, HARD (10+5)MG	RAMI-AMLO CAPSULE, HARD (10+5)MG	2118/23T, 2275/23T	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
RAMI-AMLO CAPSULE,	RAMI-AMLO CAPSULE,	2117/23T, 2274/23T	IASIS PHARMACEU	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

HARD (10+10)MG	HARD (10+10)MG		TICALS HELLAS SA	MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
RAMI-AMLO CAPSULE, HARD (5+5)MG	RAMI-AMLO CAPSULE, HARD (5+5)MG	2120/23T, 2277/23T	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
CUTIVATE CREAM 0.05%	CUTIVATE CREAM 0.05%	8287/23T, 8288/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I z) Changes (Safety/Efficacy) to 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 C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CANESTEN CREAM 1%	CANESTEN CREAM 1%	9562/23T	BAYER HELLAS ABEE	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place
CANESTEN CUTANEOUS SOLUTION 1%	CANESTEN CUTANEOUS SOLUTION 1%	9561/23T	BAYER HELLAS ABEE	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place
CANESTEN CUTANEOUS SOLUTION 1%	CANESTEN CUTANEOUS SOLUTION 1%	9561/23T	BAYER HELLAS ABEE	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the

				manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place
CANESTEN VAGINAL TABLET 500MG	CANESTEN VAGINAL TABLET 500MG	9560/23T	BAYER HELLAS ABEE	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place
SEROXAT TABLET, FILM COATED 20MG	SEROXAT TABLET, FILM COATED 20MG	6157/23T	GLAXOSMITH KLINE (IRELAND) LIMITED	B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place 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
TRIVERAM TABLET, FILM COATED 40MG/10MG/10MG	TRIVERAM TABLET, FILM COATED 40MG/10MG/10MG	4872/23T	LES LABORATOIRES SERVIER	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TRIVERAM TABLET, FILM COATED 20MG/10MG/5MG	TRIVERAM TABLET, FILM COATED 20MG/10MG/5MG	4870/23T	LES LABORATOIRES SERVIER	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

TRIVERAM TABLET, FILM COATED 20MG/5MG/ 5MG	TRIVERAM TABLET, FILM COATED 20MG/5MG/ 5MG	4869/23T	LES LABORATOIR ES SERVIER	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TRIVERAM TABLET, FILM COATED 10MG/5MG/ 5MG	TRIVERAM TABLET, FILM COATED 10MG/5MG/ 5MG	4868/23T	LES LABORATOIR ES SERVIER	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TRIVERAM TABLET, FILM COATED 20MG/10M G/10MG	TRIVERAM TABLET, FILM COATED 20MG/10M G/10MG	4871/23T	LES LABORATOIR ES SERVIER	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
BENDAMU STINE ACCORD POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 2.5MG/ML	BENDAMU STINE ACCORD POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 2.5MG/ML	7786/23T	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
MITOMYCI N ACCORD POWDER FOR SOLUTION FOR INJECTION /INFUSION 20MG/VIAL	MITOMYCI N ACCORD POWDER FOR SOLUTION FOR INJECTION /INFUSION 20MG/VIAL	8690/23T	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
TOSTRAN GEL 2%	TOSTRAN GEL 2%	7100/23T	KYOWA KIRIN HOLDINGS B.V.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
MITOMYCI N ACCORD POWDER FOR SOLUTION FOR INJECTION /INFUSION 20MG/VIAL	MITOMYCI N ACCORD POWDER FOR SOLUTION FOR INJECTION /INFUSION 20MG/VIAL	8710/23T	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
VALSARTAN JUBILANT TABLET, FILM COATED 80MG	VALSARTAN JUBILANT TABLET, FILM COATED 80MG	9096/23T, 9097/23T, 9098/23T	JUBILANT PHARMACEUTICALS NV	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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
VALSARTAN JUBILANT TABLET, FILM COATED 40MG	VALSARTAN JUBILANT TABLET, FILM COATED 40MG	9099/23T, 9100/23T, 9101/23T	JUBILANT PHARMACEUTICALS NV	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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
VALSARTAN JUBILANT TABLET, FILM COATED 160MG	VALSARTAN JUBILANT TABLET, FILM COATED 160MG	9093/23T, 9094/23T, 9095/23T	JUBILANT PHARMACEUTICALS NV	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name

				and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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
PENOPEN TABLET, FILM COATED 1G	PENOPEN TABLET, FILM COATED 1G	8540/23T	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
PENOPEN TABLET, FILM COATED 800MG	PENOPEN TABLET, FILM COATED 800MG	8541/23T	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
TENORETIC TABLET, FILM COATED 100MG/25MG	TENORETIC TABLET, FILM COATED 100MG/25MG	9608/23T, 9609/23T, 9610/23T	ATNAHS PHARMA NETHERLANDS B.V.	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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
PIPERACILLIN + TAZOBACT	PIPERACILLIN + TAZOBACT	5932/23T	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented)

AM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (2G/0.25G)/ VIAL	AM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (2G/0.25G)/ VIAL			name of the medicinal product - for Nationally Authorised Products
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (4G/0.5G)/VIAL	PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (4G/0.5G)/VIAL	5931/23T	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
TRIATEC PLUS TABLET 5MG/25MG	TRIATEC PLUS TABLET 5MG/25MG	8686/23T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 500IU	8278/23T, 8279/23T	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 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
OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 1000IU	OCTAPLEX POWDER AND SOLVENT FOR SOLUTION FOR INFUSION 1000IU	8276/23T, 8277/23T	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 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
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR	OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR	8274/23T, 8275/23T	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

INJECTION 500IU/VIAL (100IU/ML)	INJECTION 500IU/VIAL (100IU/ML)			the manufacturing process of 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.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
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/VIAL(100IU/ML)	OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/VIAL(100IU/ML)	8272/23T, 8273/23T	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 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
CO-DIOVAN TABLET, FILM COATED 80/12.5MG	CO-DIOVAN TABLET, FILM COATED 80/12.5MG	5455/23T	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
DIOVAN TABLET, FILM COATED 160MG	DIOVAN TABLET, FILM COATED 160MG	5450/23T	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
DIOVAN TABLET, FILM COATED 80MG	DIOVAN TABLET, FILM COATED 80MG	5451/23T	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

DIOVAN TABLET, FILM COATED 40MG	DIOVAN TABLET, FILM COATED 40MG	5452/23T	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
CO-DIOVAN TABLET, FILM COATED 160/25MG	CO-DIOVAN TABLET, FILM COATED 160/25MG	5453/23T	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
CO-DIOVAN TABLET, FILM COATED 160/12.5MG	CO-DIOVAN TABLET, FILM COATED 160/12.5MG	5454/23T	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
DIOVAN ORAL SOLUTION 3MG/ML	DIOVAN ORAL SOLUTION 3MG/ML	5449/23T	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
SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	4689/23T, 4690/23T, 4691/23T, 4692/23T, 4693/23T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active

				substance B.I.b.1.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
YANIMO RESPIMAT SOLUTION FOR INHALATIO N	YANIMO RESPIMAT SOLUTION FOR INHALATIO N	4684/23T, 4685/23T, 4686/23T, 4687/23T, 4688/23T	BOEHRINGER INGELHEIM INTERNATION AL GMBH	B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.b.1.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
CO-DIOVAN TABLET, FILM COATED 80/12.5MG	CO-DIOVAN TABLET, FILM COATED 80/12.5MG	7044/23T	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)
CO-DIOVAN TABLET, FILM COATED 160/25MG	CO-DIOVAN TABLET, FILM COATED 160/25MG	7042/23T	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)
DIOVAN TABLET, FILM COATED 160MG	DIOVAN TABLET, FILM COATED 160MG	7046/23T	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)
DIOVAN TABLET, FILM COATED 160MG	DIOVAN TABLET, FILM COATED 160MG	7046/23T	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)
DIOVAN TABLET, FILM COATED 40MG	DIOVAN TABLET, FILM COATED 40MG	7047/23T	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)
DIOVAN TABLET, FILM COATED 40MG	DIOVAN TABLET, FILM COATED 40MG	7047/23T	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)
DIOVAN TABLET, FILM COATED 80MG	DIOVAN TABLET, FILM COATED 80MG	7045/23T	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)
DIOVAN TABLET, FILM COATED 80MG	DIOVAN TABLET, FILM COATED 80MG	7045/23T	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)
CO-DIOVAN TABLET, FILM COATED 160/12.5MG	CO-DIOVAN TABLET, FILM COATED 160/12.5MG	7043/23T	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)
DIOVAN ORAL SOLUTION 3MG/ML	DIOVAN ORAL SOLUTION 3MG/ML	7048/23T	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)
DIOVAN ORAL SOLUTION 3MG/ML	DIOVAN ORAL SOLUTION 3MG/ML	7048/23T	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)
DELIPOST TABLET, FILM COATED 40MG	DELIPOST TABLET, FILM COATED 40MG	7275/23T	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 10MG	DELIPOST TABLET, FILM COATED 10MG	7277/23T	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	DELIPOST TABLET, FILM COATED 20MG	7276/23T	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
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	1128/23T	NOVO NORDISK A/S	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*
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	1127/23T	NOVO NORDISK A/S	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*
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	1129/23T	NOVO NORDISK A/S	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*
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	1126/23T	NOVO NORDISK A/S	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*
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	1124/23T	NOVO NORDISK A/S	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*
NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	NORDITROPIN NORDIFLEX SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	1125/23T	NOVO NORDISK A/S	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*
SINGULAIR TABLET, CHEWABLE 4MG	SINGULAIR TABLET, CHEWABLE 4MG	8162/23T	N.V. ORGANON	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
INEGY TABLET 10MG/80MG	INEGY TABLET 10MG/80MG	8157/23T	N.V. ORGANON	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
COZAAR TABLET, FILM COATED 12.5MG	COZAAR TABLET, FILM COATED 12.5MG	8165/23T	N.V. ORGANON	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
EZETROL TABLET 10MG	EZETROL TABLET 10MG	8163/23T	N.V. ORGANON	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
INEGY TABLET 10MG/10MG	INEGY TABLET 10MG/10MG	8160/23T	N.V. ORGANON	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
INEGY TABLET 10MG/20MG	INEGY TABLET 10MG/20MG	8159/23T	N.V. ORGANON	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
LIPTRUZET TABLET, FILM COATED 10MG/40MG	LIPTRUZET TABLET, FILM COATED 10MG/40MG	8167/23T	N.V. ORGANON	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
LIPTRUZET TABLET, FILM COATED 10MG/80MG	LIPTRUZET TABLET, FILM COATED 10MG/80MG	8166/23T	N.V. ORGANON	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
INEGY TABLET 10MG/40MG	INEGY TABLET 10MG/40MG	8158/23T	N.V. ORGANON	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
LIPTRUZET TABLET, FILM COATED	LIPTRUZET TABLET, FILM COATED	8168/23T	N.V. ORGANON	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction

10MG/20MG	10MG/20MG			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
LIPTRUZET TABLET, FILM COATED 10MG/10MG	LIPTRUZET TABLET, FILM COATED 10MG/10MG	8169/23T	N.V. ORGANON	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
REMERON TABLET, FILM COATED 30MG	REMERON TABLET, FILM COATED 30MG	8170/23T	N.V. ORGANON	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
SINGULAIR GRANULES FOR ORAL SUSPENSION 4MG	SINGULAIR GRANULES FOR ORAL SUSPENSION 4MG	8161/23T	N.V. ORGANON	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
COZAAR TABLET, FILM COATED 50MG	COZAAR TABLET, FILM COATED 50MG	8164/23T	N.V. ORGANON	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
ARCOXIA TABLET, FILM COATED 120MG	ARCOXIA TABLET, FILM COATED 120MG	8154/23T	N.V. ORGANON	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
ARCOXIA TABLET,	ARCOXIA TABLET,	8156/23T	N.V. ORGANON	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

FILM COATED 60MG	FILM COATED 60MG			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
ARCOXIA TABLET, FILM COATED 90MG	ARCOXIA TABLET, FILM COATED 90MG	8155/23T	N.V. ORGANON	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
EPLERENONE ACCORD TABLET, FILM COATED 25MG	EPLERENONE ACCORD TABLET, FILM COATED 25MG	8692/23T	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
EPLERENONE ACCORD TABLET, FILM COATED 50MG	EPLERENONE ACCORD TABLET, FILM COATED 50MG	8691/23T	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
HALDOL DECANOAS INJECTION 100MG/1ML	HALDOL DECANOAS INJECTION 100MG/1ML	8712/23T	JANSSEN-CILAG INTERNATIONAL NV	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
HALDOL DECANOAS INJECTION 50MG/1ML	HALDOL DECANOAS INJECTION 50MG/1ML	8713/23T	JANSSEN-CILAG INTERNATIONAL NV	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
BROXIVAN ORAL SOLUTION 6MG/ML	BROXIVAN ORAL SOLUTION 6MG/ML	6006/23T, 6007/23T	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
BROXIVAN ORAL SOLUTION 3MG/ML	BROXIVAN ORAL SOLUTION 3MG/ML	6008/23T, 6009/23T	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
GYNOFLORAN CAPSULE, HARD 50MG	GYNOFLORAN CAPSULE, HARD 50MG	9276/23T	CODAL-SYNTO 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
GYNOFLORAN CAPSULE, HARD 150MG	GYNOFLORAN CAPSULE, HARD 150MG	9275/23T	CODAL-SYNTO 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
BRALTUS INHALATION POWDER, HARD CAPSULE 10MCG	BRALTUS INHALATION POWDER, HARD CAPSULE 10MCG	6923/23T	TEVA BV	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
GLYCERINE MICROCLYSMA FOR ADULTS ENEMA 2.4G/DOSE (2,5ML)	GLYCERINE MICROCLYSMA FOR ADULTS ENEMA 2.4G/DOSE (2,5ML)	9322/23T	COSTAKIS TSISIOS & CO. 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
NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	8205/23T, 8206/23T	RAFARM S.A.	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
PAZOREM TABLET, FILM COATED 200MG	PAZOREM TABLET, FILM COATED 200MG	351/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

PAZOREM TABLET, FILM COATED 400MG	PAZOREM TABLET, FILM COATED 400MG	350/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LORANS TABLET 2MG	LORANS TABLET 2MG	9524/23T	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)*
LORANS TABLET 1MG	LORANS TABLET 1MG	9525/23T	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)*
IRINOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	IRINOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	5118/23T	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
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01 MG/ML	DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01 MG/ML	329/23T	INIBSA DENTAL S.L.U.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005 MG/ML	DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005 MG/ML	328/23T	INIBSA DENTAL S.L.U.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
STEROFUNDIN ISO SOLUTION FOR INFUSION	STEROFUNDIN ISO SOLUTION FOR INFUSION	8566/23T, 8567/23T, 8568/23T	B. BRAUN MELSUNGEN AG	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
ALBUNORM 20% SOLUTION FOR	ALBUNORM 20% SOLUTION FOR	8949/23T, 8950/23T	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 -

INFUSION 200G/L	INFUSION 200G/L			Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUNORM 25% SOLUTION FOR INFUSION 250G/L	ALBUNORM 25% SOLUTION FOR INFUSION 250G/L	8947/23T, 8948/23T	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 product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUNORM 5% SOLUTION FOR INFUSION 50G/L	ALBUNORM 5% SOLUTION FOR INFUSION 50G/L	8953/23T, 8954/23T	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 product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ALBUNORM 4% SOLUTION FOR INFUSION 40G/L	ALBUNORM 4% SOLUTION FOR INFUSION 40G/L	8951/23T, 8952/23T	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 product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
ROCURONIUM B.BRAUN SOLUTION FOR INJECTION OR INFUSION 10MG/ML	ROCURONIUM B.BRAUN SOLUTION FOR INJECTION OR INFUSION 10MG/ML	6186/23T	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
PHOXILIUM SOLUTION FOR HAEMOFILTRATION, HAEMODIAFILTRATION AND HAEMODIALYSIS	PHOXILIUM SOLUTION FOR HAEMOFILTRATION, HAEMODIAFILTRATION AND HAEMODIALYSIS	8042/23T	BAXTER HOLDING 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 - Other changes
BIOSONIDE NEBULISE	BIOSONIDE NEBULISE	9311/23T	HELP S.A.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

R SUSPENSION 0.5MG/2ML	R SUSPENSION 0.5MG/2ML			MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BIOSONIDE NEBULISER SUSPENSION 1MG/2ML	BIOSONIDE NEBULISER SUSPENSION 1MG/2ML	9310/23T	HELP 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
INFANRIX TETRA SUSPENSION FOR INJECTION	INFANRIX TETRA SUSPENSION FOR INJECTION	8705/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)
CLARIPEN TABLET, FILM COATED 500MG	CLARIPEN TABLET, FILM COATED 500MG	5264/22T, 5265/22T, 5266/22T, 5267/22T, 5268/22T, 5269/22T	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 C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
CILODRAL TABLET, FILM COATED 10MG	CILODRAL TABLET, FILM COATED 10MG	9450/23T	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
CILODRAL TABLET, FILM COATED 40MG	CILODRAL TABLET, FILM COATED 40MG	9448/23T	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
CILODRAL TABLET, FILM COATED 20MG	CILODRAL TABLET, FILM COATED 20MG	9449/23T	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
MYCORIL CREAM 1% W/W	MYCORIL CREAM 1% W/W	9121/23T, 9122/23T	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
BOTAFEX CUTANEOUS SOLUTION 5% (W/V)	BOTAFEX CUTANEOUS SOLUTION 5% (W/V)	9378/23T	PHARMEX 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
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1200IU	MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1200IU	1326/23T	FERRING HELLAS MEPE	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
MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 600IU	MENOPUR POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 600IU	1327/23T	FERRING HELLAS MEPE	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
ATANTO CAPSULE, HARD 80MG	ATANTO CAPSULE, HARD 80MG	8694/23T	PHARMATHEN S.A.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
ATANTO CAPSULE,	ATANTO CAPSULE,	8693/23T	PHARMATHEN S.A.	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

HARD 125MG AND 80MG	HARD 125MG AND 80MG			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
PRAGIOLA CAPSULE, HARD 75MG	PRAGIOLA CAPSULE, HARD 75MG	8332/23T, 8333/23T	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
PRAGIOLA CAPSULE, HARD 300MG	PRAGIOLA CAPSULE, HARD 300MG	8328/23T, 8329/23T	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
PRAGIOLA CAPSULE, HARD 25MG	PRAGIOLA CAPSULE, HARD 25MG	8334/23T, 8335/23T	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
PRAGIOLA CAPSULE, HARD 150MG	PRAGIOLA CAPSULE, HARD 150MG	8330/23T, 8331/23T	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
AUGMENTIN TABLET, FILM COATED 1G	AUGMENTIN TABLET, FILM COATED 1G	1586/23T	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
AUGMENTIN POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	AUGMENTIN POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	1588/23T	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
AUGMENTIN TABLET, FILM COATED 500MG/125MG	AUGMENTIN TABLET, FILM COATED 500MG/125MG	1587/23T	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
AUGMENTIN MIXED FRUIT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	AUGMENTIN MIXED FRUIT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	1589/23T	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
AUGMENTIN ES POWDER FOR ORAL SUSPENSION (600+42.9)MG/5ML	AUGMENTIN ES POWDER FOR ORAL SUSPENSION (600+42.9)MG/5ML	1585/23T	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
LIPOCAT TABLET, FILM COATED 10MG/20MG	LIPOCAT TABLET, FILM COATED 10MG/20MG	4332/23T, 4333/23T, 4334/23T	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
LIPOCAT TABLET, FILM COATED 10MG/80MG	LIPOCAT TABLET, FILM COATED 10MG/80MG	4326/23T, 4327/23T, 4328/23T	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
LIPOCAT TABLET, FILM COATED 10MG/10MG	LIPOCAT TABLET, FILM COATED 10MG/10MG	4335/23T, 4336/23T, 4337/23T	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
LIPOCAT TABLET, FILM COATED 10MG/40MG	LIPOCAT TABLET, FILM COATED 10MG/40MG	4329/23T, 4330/23T, 4331/23T	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
FLUDARABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTION 25MG/ML	FLUDARABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTION 25MG/ML	4354/23T	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5MCG	SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5MCG	7867/23T, 7868/23T, 7869/23T	ASTRAZENECA AB	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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)
SOFTACORT EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 3.35MG/ML	SOFTACORT EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER 3.35MG/ML	7870/23T	LABORATOIRES THEA	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
CANDEPRESS COMP TABLET 16MG/12.5 MG	CANDEPRESS COMP TABLET 16MG/12.5 MG	9348/23T, 9349/23T	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
CANDEPRESS COMP TABLET 8MG/12.5MG	CANDEPRESS COMP TABLET 8MG/12.5MG	9350/23T, 9351/23T	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
MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	4666/23T	CASEN RECORDATI SL	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
SYMBICORT TURBUHALER POWDER FOR INHALATION 320MCG/9MCG	SYMBICORT TURBUHALER POWDER FOR INHALATION 320MCG/9MCG	7871/23T, 7872/23T, 7873/23T	ASTRAZENECA AB	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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)
SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	7874/23T, 7875/23T, 7876/23T	ASTRAZENECA AB	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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)
SETROPAL SOLUTION FOR INJECTION 250MCG/5ML	SETROPAL SOLUTION FOR INJECTION 250MCG/5ML	5678/23T	CODAL-SYNTO LIMITED	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	8973/23T	CODAL-SYNTO LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	8972/23T	CODAL-SYNTO LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF

KAPETRAL TABLET, FILM COATED 150MG	KAPETRAL TABLET, FILM COATED 150MG	8586/23T	REMEDICA LTD	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
KAPETRAL TABLET, FILM COATED 500MG	KAPETRAL TABLET, FILM COATED 500MG	8585/23T	REMEDICA LTD	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
HALDOL ORAL SOLUTION 2MG/ML	HALDOL ORAL SOLUTION 2MG/ML	8675/23T	JANSSEN-CILAG INTERNATIONAL NV	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
PROLUTEX SOLUTION FOR INJECTION 25MG	PROLUTEX SOLUTION FOR INJECTION 25MG	8404/23T, 8405/23T, 8406/23T	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 do not include batch release
SEPTANEST SOLUTION FOR INJECTION (40MG/5MCG)/ML	SEPTANEST SOLUTION FOR INJECTION (40MG/5MCG)/ML	8320/23T	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	SEPTANEST FORTE SOLUTION FOR INJECTION (40MG/10MCG)/ML	8319/23T	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
RIVAROXABAN/RAFARM TABLET, FILM COATED 2.5MG	RIVAROXABAN/RAFARM TABLET, FILM COATED 2.5MG	7841/23T	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

RIVAROXABAN/RAFARM TABLET, FILM COATED 15MG AND 20MG	RIVAROXABAN/RAFARM TABLET, FILM COATED 15MG AND 20MG	7837/23T	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
RIVAROXABAN/RAFARM TABLET, FILM COATED 20MG	RIVAROXABAN/RAFARM TABLET, FILM COATED 20MG	7838/23T	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
RIVAROXABAN/RAFARM TABLET, FILM COATED 15MG	RIVAROXABAN/RAFARM TABLET, FILM COATED 15MG	7839/23T	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
RIVAROXABAN/RAFARM TABLET, FILM COATED 10MG	RIVAROXABAN/RAFARM TABLET, FILM COATED 10MG	7840/23T	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
SOLIFENACIN SANDOZ TABLET, FILM COATED 10MG	SOLIFENACIN SANDOZ TABLET, FILM COATED 10MG	8000/23T	SANDOZ 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
SOLIFENACIN SANDOZ TABLET, FILM COATED 5MG	SOLIFENACIN SANDOZ TABLET, FILM COATED 5MG	7999/23T	SANDOZ 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

DUODART CAPSULE, HARD	DUODART CAPSULE, HARD	8475/23T, 8476/23T	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already 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)*
IMODIUM PLUS TABLET 2MG/125MG	IMODIUM PLUS TABLET 2MG/125MG	7214/23T, 7215/23T, 7216/23T, 7217/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ALFUZOSIN AUROBINDO TABLET, PROLONGED-RELEASE 10MG	ALFUZOSIN AUROBINDO TABLET, PROLONGED-RELEASE 10MG	4359/23T	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)*
TORVACARD NEO TABLET, FILM COATED 40MG	TORVACARD NEO TABLET, FILM COATED 40MG	4949/23T	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TORVACARD NEO TABLET, FILM COATED 20MG	TORVACARD NEO TABLET, FILM COATED 20MG	4950/23T	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TORVACARD NEO TABLET, FILM	TORVACARD NEO TABLET, FILM	4951/23T	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For

COATED 10MG	COATED 10MG			an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SOLIFENACIN SANDOZ TABLET, FILM COATED 10MG	SOLIFENACIN SANDOZ TABLET, FILM COATED 10MG	6173/23T	SANDOZ GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
SOLIFENACIN SANDOZ TABLET, FILM COATED 5MG	SOLIFENACIN SANDOZ TABLET, FILM COATED 5MG	6174/23T	SANDOZ GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
SERTRALINE ACCORD TABLET, FILM COATED 50MG	SERTRALINE ACCORD TABLET, FILM COATED 50MG	7918/23T, 7919/23T	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 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
SERTRALINE ACCORD TABLET, FILM COATED 100MG	SERTRALINE ACCORD TABLET, FILM COATED 100MG	7916/23T, 7917/23T	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 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
SERTRALINE ACCORD TABLET, FILM COATED 50MG	SERTRALINE ACCORD TABLET, FILM COATED 50MG	7068/23T	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

SERTRALINE ACCORD TABLET, FILM COATED 100MG	SERTRALINE ACCORD TABLET, FILM COATED 100MG	7067/23T	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
SERTRALINE ACCORD TABLET, FILM COATED 50MG	SERTRALINE ACCORD TABLET, FILM COATED 50MG	7133/23T, 7134/23T	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 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)
SERTRALINE ACCORD TABLET, FILM COATED 100MG	SERTRALINE ACCORD TABLET, FILM COATED 100MG	7131/23T, 7132/23T	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 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)
SERTRALINE ACCORD TABLET, FILM COATED 50MG	SERTRALINE ACCORD TABLET, FILM COATED 50MG	null	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
MELOREM TABLET 7.5MG	MELOREM TABLET 7.5MG	9464/23T, 9465/23T, 9466/23T	REMEDICA LTD	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w A.7 A.7 - ADMINISTRATIVE CHANGES

				- Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MELOREM TABLET 15MG	MELOREM TABLET 15MG	9461/23T, 9462/23T, 9463/23T	REMEDICA LTD	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification w A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	8617/23T, 8618/23T, 8619/23T	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
SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	8614/23T, 8615/23T, 8616/23T	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
ABACAVIR ACCORD TABLET, FILM COATED 300MG	ABACAVIR ACCORD TABLET, FILM COATED 300MG	8699/23T	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
NOPRILAM 250 POWDER FOR ORAL SUSPENSION	NOPRILAM 250 POWDER FOR ORAL SUSPENSION	9476/23T	BIAL-PORTELA & CA, SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)

(250MG/62.5MG)/5ML	(250MG/62.5MG)/5ML			
NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	9477/23T	BIAL-PORTELA & CA, SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
LENALIDOMIDE NORAMEDA CAPSULE, HARD 10MG	LENALIDOMIDE NORAMEDA CAPSULE, HARD 10MG	7282/23T, 7283/23T	UAB NORAMEDA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 NORAMEDA CAPSULE, HARD 5MG	LENALIDOMIDE NORAMEDA CAPSULE, HARD 5MG	7284/23T, 7285/23T	UAB NORAMEDA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 NORAMEDA CAPSULE, HARD 15MG	LENALIDOMIDE NORAMEDA CAPSULE, HARD 15MG	7280/23T, 7281/23T	UAB NORAMEDA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 NORAMEDA CAPSULE, HARD 25MG	LENALIDOMIDE NORAMEDA CAPSULE, HARD 25MG	7278/23T, 7279/23T	UAB NORAMEDA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
NOPRILAM DT TABLET, FILM COATED 1000MG	NOPRILAM DT TABLET, FILM COATED 1000MG	9470/23T, 9471/23T, 9472/23T, 9473/23T	BIAL-PORTELA & CA, SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)

STRABEN LOZENGE 8.75MG	STRABEN LOZENGE 8.75MG	9495/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES 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)
CANDESARTAN KRKA TABLET 4MG	CANDESARTAN KRKA TABLET 4MG	8572/23T	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	CANDESARTAN KRKA TABLET 8MG	8571/23T	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	CANDESARTAN KRKA TABLET 32MG	8569/23T	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 16MG	CANDESARTAN KRKA TABLET 16MG	8570/23T	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
DIAMICRON MODIFIED-RELEASE TABLET 30MG	DIAMICRON MODIFIED-RELEASE TABLET 30MG	10372/20T	LES LABORATOIRES SERVIER	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*

DIAMICRON MODIFIED-RELEASE TABLET 30MG	DIAMICRON MODIFIED-RELEASE TABLET 30MG	5081/21T	LES LABORATOIRES SERVIER	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DIAMICRON MODIFIED-RELEASE TABLET 60MG	DIAMICRON MODIFIED-RELEASE TABLET 60MG	5082/21T	LES LABORATOIRES SERVIER	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
BUTAMED SYRUP 7.5MG/5ML	BUTAMED SYRUP 7.5MG/5ML	9123/23T	SAPIENS PHARMACEUTICALS LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
NOPRILAM 250 POWDER FOR ORAL SUSPENSION (250MG/62.5MG)/5ML	NOPRILAM 250 POWDER FOR ORAL SUSPENSION (250MG/62.5MG)/5ML	9329/23T, 9330/23T	BIAL-PORTELA & CA, 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 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)
NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	9331/23T, 9332/23T	BIAL-PORTELA & CA, 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 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)
CELEBREX CAPSULE, HARD 200MG	CELEBREX CAPSULE, HARD 200MG	8254/23T, 8255/23T, 8256/23T, 8257/23T, 8258/23T	VIATRIS HELLAS LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for

				importation A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
CELEBREX CAPSULE, HARD 100MG	CELEBREX CAPSULE, HARD 100MG	8259/23T, 8260/23T, 8261/23T, 8262/23T, 8263/23T	VIATRIS HELLAS LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
ALBUNORM 20% SOLUTION FOR INFUSION 200G/L	ALBUNORM 20% SOLUTION FOR INFUSION 200G/L	4186/23T, 4187/23T, 4188/23T	OCTAPHARMA (IP) SPRL	B.I.a.3.c B.I.a.3.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The change requires assessment of the comparability of a biological/immunological active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in 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
ALBUNORM 5% SOLUTION	ALBUNORM 5% SOLUTION	4192/23T, 4193/23T, 4194/23T	OCTAPHARMA (IP) SPRL	B.I.a.3.c B.I.a.3.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size

FOR INFUSION 50G/L	FOR INFUSION 50G/L			(including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The change requires assessment of the comparability of a biological/immunological active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in 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
ALBUNOR M 25% SOLUTION FOR INFUSION 250G/L	ALBUNOR M 25% SOLUTION FOR INFUSION 250G/L	4183/23T, 4184/23T, 4185/23T	OCTAPHARMA (IP) SPRL	B.I.a.3.c B.I.a.3.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The change requires assessment of the comparability of a biological/immunological active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in 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
ALBUNOR M 4% SOLUTION FOR INFUSION 40G/L	ALBUNOR M 4% SOLUTION FOR INFUSION 40G/L	4189/23T, 4190/23T, 4191/23T	OCTAPHARMA (IP) SPRL	B.I.a.3.c B.I.a.3.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The change requires assessment of the comparability of a biological/immunological active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the

				manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in 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
IRINOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	IRINOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	3882/23T, 3883/23T	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
EZETIMIBE /MYLAN TABLET 10MG	EZETIMIBE /MYLAN TABLET 10MG	3000/23T	MYLAN PHARMACEUTICALS 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)
NEBIDO SOLUTION FOR INJECTION 1000MG/4ML	NEBIDO SOLUTION FOR INJECTION 1000MG/4ML	7770/23T	BAYER HELLAS ABEE	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)
REGAINE WOMEN'S FOAM CUTANEOUS FOAM 5% W/W	REGAINE WOMEN'S FOAM CUTANEOUS FOAM 5% W/W	8859/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 2.27 % W/V/22.7 MG/ML	PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 2.27 % W/V/22.7 MG/ML	2690/23T, 2691/23T, 2692/23T, 2693/23T, 2694/23T, 2695/23T, 2696/23T, 2697/23T, 2698/23T, 2699/23T, 2700/23T, 5694/23T	BAXTER (HELLAS) EPE	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test proc B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test B.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 B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc
PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 3.86 % W/V/38.6 MG/ML	PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 3.86 % W/V/38.6 MG/ML	2679/23T, 2680/23T, 2681/23T, 2682/23T, 2683/23T, 2684/23T, 2685/23T, 2686/23T, 2687/23T, 2688/23T, 2689/23T, 5693/23T	BAXTER (HELLAS) EPE	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test proc B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test B.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 B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc
PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 1.36 % W/V/13.6 MG/ML	PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 1.36 % W/V/13.6 MG/ML	2701/23T, 2702/23T, 2703/23T, 2704/23T, 2705/23T, 2706/23T, 2707/23T, 2708/23T, 2709/23T, 2710/23T, 2711/23T, 5695/23T	BAXTER (HELLAS) EPE	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.d.2.b B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test proc B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test B.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 B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc
ASPIRIN TABLET 500MG	ASPIRIN TABLET 500MG	9831/22T	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

ASPIRIN TABLET 500MG	ASPIRIN TABLET 500MG	9831/22T	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
ASPRO CLEAR EFFERVES CENT TABLET 300MG	ASPRO CLEAR EFFERVES CENT TABLET 300MG	9829/22T	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
ASPRO CLEAR EFFERVES CENT TABLET 300MG	ASPRO CLEAR EFFERVES CENT TABLET 300MG	9829/22T	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
ASPIRIN EXPRESS TABLET, COATED 500MG	ASPIRIN EXPRESS TABLET, COATED 500MG	9833/22T	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
ASPIRIN EXPRESS TABLET, COATED 500MG	ASPIRIN EXPRESS TABLET, COATED 500MG	9833/22T	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
ASPIRIN EC TABLET, GASTRO-RESISTAN T 100MG	ASPIRIN EC TABLET, GASTRO-RESISTAN T 100MG	9830/22T	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
ASPIRIN EC TABLET, GASTRO-RESISTAN T 100MG	ASPIRIN EC TABLET, GASTRO-RESISTAN T 100MG	9830/22T	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
ASPIRIN-C EFFERVES CENT TABLET	ASPIRIN-C EFFERVES CENT TABLET	9832/22T	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
ASPIRIN-C EFFERVES CENT TABLET	ASPIRIN-C EFFERVES CENT TABLET	9832/22T	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
ANASTROZOLE ACCORD TABLET, FILM COATED 1MG	ANASTROZOLE ACCORD TABLET, FILM COATED 1MG	8481/23T	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
TENOVIRAL TABLET, FILM COATED 163MG	TENOVIRAL TABLET, FILM COATED 163MG	4280/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TENOVIRAL TABLET, FILM COATED 204MG	TENOVIRAL TABLET, FILM COATED 204MG	4279/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	7138/23T	SAPIENS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
TEMELIN TABLET, FILM COATED 10MG	TEMELIN TABLET, FILM COATED 10MG	5539/23T, 5540/23T, 5541/23T, 5542/23T	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
REGAINE MEN'S FOAM CUTANEOUS FOAM 5% W/W	REGAINE MEN'S FOAM CUTANEOUS FOAM 5% W/W	9333/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 20MG	ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 20MG	7365/23T	TAD PHARMA GMBH	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
TRIACOR TABLET, PROLONGED-RELEASE 5MG/5MG	TRIACOR TABLET, PROLONGED-RELEASE 5MG/5MG	9408/23T	SANOFI WINTHROP INDUSTRIE.	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

ABSKEN TABLET, FILM COATED 1MG	ABSKEN TABLET, FILM COATED 1MG	4141/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
ABSKEN TABLET, FILM COATED 2MG	ABSKEN TABLET, FILM COATED 2MG	4140/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
PACLITAXEL ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXEL ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	3718/23T	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
CELMANTIN TABLET, FILM COATED 40MG	CELMANTIN TABLET, FILM COATED 40MG	2529/23T	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
CELMANTIN TABLET, FILM COATED 10MG	CELMANTIN TABLET, FILM COATED 10MG	2531/23T	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
CELMANTIN TABLET, FILM COATED 5MG	CELMANTIN TABLET, FILM COATED 5MG	2532/23T	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
CELMANTIN TABLET, FILM COATED 20MG	CELMANTIN TABLET, FILM COATED 20MG	2530/23T	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

ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	8291/23T	SANOFI PASTEUR.	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
LOSARTAN AUROBINDO TABLET, FILM COATED 50MG	LOSARTAN AUROBINDO TABLET, FILM COATED 50MG	3713/23T	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
SALOFALK TABLET, GASTRO-RESISTANT 1G	SALOFALK TABLET, GASTRO-RESISTANT 1G	8799/23T, 8800/23T, 8801/23T	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*
CLOMENTIN TABLET, FILM COATED 10MG	CLOMENTIN TABLET, FILM COATED 10MG	8412/23T	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
CLOMENTIN TABLET, FILM COATED 20MG	CLOMENTIN TABLET, FILM COATED 20MG	8410/23T	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
CLOMENTIN TABLET, FILM COATED 5MG	CLOMENTIN TABLET, FILM COATED 5MG	8413/23T	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
CLOMENTIN TABLET, FILM COATED 15MG	CLOMENTIN TABLET, FILM COATED 15MG	8411/23T	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	FEMOSTON TABLET, FILM COATED	9120/23T	VIATRIS HEALTHCARE LIMITED.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
EZETIMIBE +SIMVASTATIN/MYLAN TABLET 10MG/20MG	EZETIMIBE +SIMVASTATIN/MYLAN TABLET 10MG/20MG	8189/23T, 8190/23T, 8191/23T	MYLAN IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EZETIMIBE +SIMVASTATIN/MYLAN TABLET 10MG/10MG	EZETIMIBE +SIMVASTATIN/MYLAN TABLET 10MG/10MG	8192/23T, 8193/23T, 8194/23T	MYLAN IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site

				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
EZETIMIBE +SIMVASTATIN/MYLAN TABLET 10MG/40MG	EZETIMIBE +SIMVASTATIN/MYLAN TABLET 10MG/40MG	8186/23T, 8187/23T, 8188/23T	MYLAN IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
RIASTAP POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	RIASTAP POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	8091/23T	CSL BEHRING 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
ORIENS VOM TABLET, SUBLINGUAL 50MG	ORIENS VOM TABLET, SUBLINGUAL 50MG	1297/23T	GALENICA 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
SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5MCG	SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5MCG	7713/23T	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SYMBICORT	SYMBICORT	7710/23T	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name

PRESSURISED INHALATION, SUSPENSION 80MCG/2.25MCG/ACTUATION	PRESSURISED INHALATION, SUSPENSION 80MCG/2.25MCG/ACTUATION			and/or address of the marketing authorisation holder
SYMBICORT PRESSURISED INHALATION, SUSPENSION 160/4.5MCG/ACTUATION	SYMBICORT PRESSURISED INHALATION, SUSPENSION 160/4.5MCG/ACTUATION	7709/23T	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 320MCG/9MCG	SYMBICORT TURBUHALER POWDER FOR INHALATION 320MCG/9MCG	7711/23T	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	SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	7712/23T	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
STOVADIS TABLET, FILM COATED 6.25MG/5MG	STOVADIS TABLET, FILM COATED 6.25MG/5MG	8362/23T	LES LABORATOIRES SERVIER	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
IVIVERZ TABLET, FILM COATED 600MG/300MG	IVIVERZ TABLET, FILM COATED 600MG/300MG	1961/22T	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
IVIVERZ TABLET, FILM COATED 600MG/300MG	IVIVERZ TABLET, FILM COATED 600MG/300MG	9274/23T	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 - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR: implementation of wording agreed by the competent authority
PANADOL SOLUBLE EFFERVESCENT TABLET 500MG	PANADOL SOLUBLE EFFERVESCENT TABLET 500MG	9170/23T, 9171/23T	HALEON HELLAS SINGLE MEMBER SOCIETE ANONYME (TRADING AS HALEON HELLAS)	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.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
DEXAMETHASONE MEDOCHEMIE SOLUTION FOR INJECTION OR INFUSION 4MG/ML	DEXAMETHASONE MEDOCHEMIE SOLUTION FOR INJECTION OR INFUSION 4MG/ML	7610/23T	MEDOCHEMIE IBERIA S.A.	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ZEPILEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	ZEPILEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	8860/23T	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
ZEPILEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	ZEPILEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	8861/23T	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
PULMOTON INHALATION POWDER, PRE-DISPENSED (400+12) MCG/DOSE	PULMOTON INHALATION POWDER, PRE-DISPENSED (400+12) MCG/DOSE	5720/22T, 5721/22T, 5722/22T, 5723/22T	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 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
PULMOTON INHALATION POWDER, PRE-DISPENSED (100+6) MCG/DOSE	PULMOTON INHALATION POWDER, PRE-DISPENSED (100+6) MCG/DOSE	5728/22T, 5729/22T, 5730/22T, 5731/22T	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 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
PULMOTON INHALATION POWDER, PRE-DISPENSED (200+6) MCG/DOSE	PULMOTON INHALATION POWDER, PRE-DISPENSED (200+6) MCG/DOSE	5724/22T, 5725/22T, 5726/22T, 5727/22T	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 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 ORAL SUSPENSION 1MG/ML	VESICARE ORAL SUSPENSION 1MG/ML	4725/23T	ASTELLAS PHARMACEUTICALS A.E.B.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LIPOPEN TABLET, FILM COATED 5MG/10MG	LIPOPEN TABLET, FILM COATED 5MG/10MG	6297/23T, 6298/23T, 6299/23T	ELPEN PHARMACEUTICAL CO INC	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LIPOPEN TABLET, FILM COATED 40MG/10MG	LIPOPEN TABLET, FILM COATED 40MG/10MG	6288/23T, 6289/23T, 6290/23T	ELPEN PHARMACEUTICAL CO INC	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LIPOPEN TABLET, FILM COATED 20MG/10MG	LIPOPEN TABLET, FILM COATED 20MG/10MG	6291/23T, 6292/23T, 6293/23T	ELPEN PHARMACEUTICAL CO INC	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product -

				Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LIPOPEN TABLET, FILM COATED 10MG/10MG	LIPOPEN TABLET, FILM COATED 10MG/10MG	6294/23T, 6295/23T, 6296/23T	ELPEN PHARMACEUTICAL CO INC	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
LIPOPEN TABLET, FILM COATED 5MG/10MG	LIPOPEN TABLET, FILM COATED 5MG/10MG	1923/23T	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
LIPOPEN TABLET, FILM COATED 10MG/10MG	LIPOPEN TABLET, FILM COATED 10MG/10MG	1922/23T	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
LIPOPEN TABLET, FILM COATED 20MG/10MG	LIPOPEN TABLET, FILM COATED 20MG/10MG	1921/23T	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
LIPOPEN TABLET, FILM COATED 40MG/10MG	LIPOPEN TABLET, FILM COATED 40MG/10MG	1920/23T	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
LIPOPEN TABLET, FILM COATED 5MG/10MG	LIPOPEN TABLET, FILM COATED 5MG/10MG	8517/22T	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LIPOPEN TABLET, FILM COATED 20MG/10MG	LIPOPEN TABLET, FILM COATED 20MG/10MG	8515/22T	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LIPOPEN TABLET, FILM COATED 40MG/10MG	LIPOPEN TABLET, FILM COATED 40MG/10MG	8514/22T	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LIPOPEN TABLET, FILM COATED 10MG/10MG	LIPOPEN TABLET, FILM COATED 10MG/10MG	8516/22T	ELPEN PHARMACEUTICAL CO INC	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ZOVIDUO CREAM (50MG/10MG)/G	ZOVIDUO CREAM (50MG/10MG)/G	8417/23T	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
OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	8416/23T	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
EMLA CREAM 5%	EMLA CREAM 5%	7191/23T, 7192/23T, 7193/23T, 7194/23T	ASPEN PHARMA TRADING LIMITED	B.I.b.1.e B.I.b.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a specification parameter which may have a significa B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or

				limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	8032/23T, 8033/23T	TEVA PHARMA BV	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
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	8034/23T, 8035/23T	TEVA PHARMA BV	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
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	8030/23T, 8031/23T	TEVA PHARMA BV	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
OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	8336/23T	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
ZOLOFT TABLET, FILM COATED 50MG	ZOLOFT TABLET, FILM COATED 50MG	3430/23T	VIATRIS HELLAS LTD	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer
ZOLOFT TABLET, FILM	ZOLOFT TABLET, FILM	3429/23T	VIATRIS HELLAS LTD	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the

COATED 100MG	COATED 100MG			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
PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	PROGRAF CONCENTRATE FOR SOLUTION FOR INFUSION 5MG/ML	7099/23T	ASTELLAS PHARMACEUTICALS A.E.B.E.	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
BLOXAZOC TABLET, PROLONGED-RELEASE 100MG	BLOXAZOC TABLET, PROLONGED-RELEASE 100MG	8477/23T	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 25MG	BLOXAZOC TABLET, PROLONGED-RELEASE 25MG	8479/23T	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 200MG	BLOXAZOC TABLET, PROLONGED-RELEASE 200MG	8480/23T	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	BLOXAZOC TABLET, PROLONGED-RELEASE 50MG	8478/23T	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
CLOZAPINE ACCORD TABLET 100MG	CLOZAPINE ACCORD TABLET 100MG	5730/23T	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
SIRODROL ORAL SOLUTION 10MG/ML	SIRODROL ORAL SOLUTION 10MG/ML	8264/23T	VIANEX S.A	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ZARATOR TABLET, FILM COATED 40MG	ZARATOR TABLET, FILM COATED 40MG	7971/23T	VIATRIS 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
LIPITOR TABLET, FILM COATED 10MG	LIPITOR TABLET, FILM COATED 10MG	7970/23T	VIATRIS 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
LIPITOR TABLET, FILM COATED 20MG	LIPITOR TABLET, FILM COATED 20MG	7969/23T	VIATRIS 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
ZARATOR TABLET, FILM COATED 10MG	ZARATOR TABLET, FILM COATED 10MG	7973/23T	VIATRIS 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
ZARATOR TABLET, FILM COATED 20MG	ZARATOR TABLET, FILM COATED 20MG	7972/23T	VIATRIS 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
LIPITOR TABLET, FILM COATED 40MG	LIPITOR TABLET, FILM COATED 40MG	7968/23T	VIATRIS 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
PRORAMACE CAPSULE, HARD	PRORAMACE CAPSULE, HARD	2462/23T, 2463/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products

2.5MG/1.25 MG	2.5MG/1.25 MG		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
PRORAMACE CAPSULE, HARD 5MG/5MG	PRORAMACE CAPSULE, HARD 5MG/5MG	2456/23T, 2457/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
PRORAMACE CAPSULE, HARD 2.5MG/2.5MG	PRORAMACE CAPSULE, HARD 2.5MG/2.5MG	2460/23T, 2461/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
PRORAMACE CAPSULE, HARD 10MG/10MG	PRORAMACE CAPSULE, HARD 10MG/10MG	2452/23T, 2453/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
PRORAMACE CAPSULE, HARD 5MG/2.5MG	PRORAMACE CAPSULE, HARD 5MG/2.5MG	2458/23T, 2459/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal

				products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
PRORAMACE CAPSULE, HARD 10MG/5MG	PRORAMACE CAPSULE, HARD 10MG/5MG	2454/23T, 2455/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
HYDROXYCHLOROQUINE SULFATE ACCORD TABLET, FILM COATED 200MG	HYDROXYCHLOROQUINE SULFATE ACCORD TABLET, FILM COATED 200MG	4077/23T	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
VALSARTAN KRKA TABLET, FILM COATED 160MG	VALSARTAN KRKA TABLET, FILM COATED 160MG	8043/23T, 8044/23T	KRKA D.D. NOVO MESTO	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
VALSARTAN KRKA TABLET, FILM COATED 80MG	VALSARTAN KRKA TABLET, FILM COATED 80MG	7997/23T	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
VALSARTAN KRKA TABLET, FILM	VALSARTAN KRKA TABLET, FILM	7996/23T	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

COATED 160MG	COATED 160MG			of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VALSARTAN KRKA TABLET, FILM COATED 320MG	VALSARTAN KRKA TABLET, FILM COATED 320MG	7995/23T	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
VALSARTAN KRKA TABLET, FILM COATED 40MG	VALSARTAN KRKA TABLET, FILM COATED 40MG	7998/23T	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
SYNTOSARTIN TABLET 300MG	SYNTOSARTIN TABLET 300MG	8722/23T, 8723/23T, 8724/23T, 8725/23T	CODAL-SYNTO LIMITED	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc
SYNTOSARTIN TABLET 150MG	SYNTOSARTIN TABLET 150MG	8726/23T, 8727/23T, 8728/23T, 8729/23T	CODAL-SYNTO LIMITED	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the

				finished product - Site where any manufacturing operation(s) take place, ex B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc
ZITHROMAX POWDER FOR ORAL SUSPENSION 200MG/5ML	ZITHROMAX POWDER FOR ORAL SUSPENSION 200MG/5ML	8698/23T	PFIZER HELLAS AE	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)
CLOMENTIN TABLET, FILM COATED 5MG	CLOMENTIN TABLET, FILM COATED 5MG	8882/23T, 8883/23T, 8884/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place 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.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
CLOMENTIN TABLET, FILM COATED 20MG	CLOMENTIN TABLET, FILM COATED 20MG	8873/23T, 8874/23T, 8875/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place 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.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
CLOMENTIN TABLET, FILM COATED 10MG	CLOMENTIN TABLET, FILM COATED 10MG	8879/23T, 8880/23T, 8881/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place 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.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
CLOMENTIN TABLET, FILM COATED 15MG	CLOMENTIN TABLET, FILM COATED 15MG	8876/23T, 8877/23T, 8878/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place 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.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
HEXARHINAL PLUS NASAL SPRAY, SOLUTION (1MG/50MG)/ML	HEXARHINAL PLUS NASAL SPRAY, SOLUTION (1MG/50MG)/ML	7416/23T, 7417/23T, 7418/23T, 7419/23T, 7420/23T, 7421/23T, 7422/23T, 7423/23T, 7424/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INTRATECT SOLUTION FOR INFUSION 100G/L	INTRATECT SOLUTION FOR INFUSION 100G/L	8180/23T	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 50G/L	INTRATECT SOLUTION FOR INFUSION 50G/L	8181/23T	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
OPTIVATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	OPTIVATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	7825/23T	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
LAMIVUDINE/ZIDOVUDINE AUROBINDO TABLET, FILM COATED 150MG/300MG	LAMIVUDINE/ZIDOVUDINE AUROBINDO TABLET, FILM COATED 150MG/300MG	3431/23T	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)*
STEROFUNDIN ISO SOLUTION FOR INFUSION	STEROFUNDIN ISO SOLUTION FOR INFUSION	7993/23T	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)
PANTAROL POWDER FOR SOLUTION FOR INJECTION 40MG	PANTAROL POWDER FOR SOLUTION FOR INJECTION 40MG	4109/23T, 4110/23T	VIANEX S.A	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - 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
ONDANSETRON ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	ONDANSETRON ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	7882/23T	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
NAIREM TABLET, FILM COATED 5MG	NAIREM TABLET, FILM COATED 5MG	6942/23T	DEMO 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)
NAIREM TABLET, FILM COATED 10MG	NAIREM TABLET, FILM COATED 10MG	6941/23T	DEMO 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)
NAIREM TABLET, FILM COATED 20MG	NAIREM TABLET, FILM COATED 20MG	6940/23T	DEMO 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)
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 40MG	PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 40MG	7053/23T	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-	PANTOPRAZOLE AUROBINDO TABLET, GASTRO-	7054/23T	AUROBINDO PHARMA (MALTA) LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

RESISTAN T 20MG	RESISTAN T 20MG			material/reagent/intermediate used in 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)
PROCTO-GLYVENOL RECTAL CREAM	PROCTO-GLYVENOL RECTAL CREAM	9006/23T	RECORDATI HELLAS PHARMACEU TICALS 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
PROCTO-GLYVENOL SUPPOSIT ORY	PROCTO-GLYVENOL SUPPOSIT ORY	9005/23T	RECORDATI HELLAS PHARMACEU TICALS 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 CAPSULE, HARD 500MG	AMOXIL CAPSULE, HARD 500MG	8245/23T	GLAXOSMITH KLINE (IRELAND) 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)
XALATAN EYE DROPS, SOLUTION 50MCG/ML	XALATAN EYE DROPS, SOLUTION 50MCG/ML	5426/23T	VIATRIS HELLAS LTD	B.II.e.1.z B.II.e.1.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Other changes
SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI ON FOR INJECTION 20MG	SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI ON FOR INJECTION 20MG	6829/23T	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI ON FOR INJECTION 30MG	SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI ON FOR INJECTION 30MG	6828/23T	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI	SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI	6830/23T	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the

ON FOR INJECTION 10MG	ON FOR INJECTION 10MG			manufacturer/importer is responsible do not include batch release
FELDENE TABLET, DISPERSIBLE 20MG	FELDENE TABLET, DISPERSIBLE 20MG	4694/23T	PFIZER HELLAS AE	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	5614/23T, 5615/23T	SANOFI PASTEUR.	B.I.a.1.a B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	6783/23T	MERZ PHARMACEUTICALS GMBH	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
XEOMIN POWDER FOR SOLUTION FOR INJECTION 200 UNITS	XEOMIN POWDER FOR SOLUTION FOR INJECTION 200 UNITS	6782/23T	MERZ PHARMACEUTICALS GMBH	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	6784/23T	MERZ PHARMACEUTICALS GMBH	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
TENEREL TABLET 1MG	TENEREL TABLET 1MG	4474/23T	MEDOCHEMIE 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
VISPRING ADVANCE EYE DROPS, SOLUTION 0.5MG/ML	VISPRING ADVANCE EYE DROPS, SOLUTION 0.5MG/ML	7943/23T	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
VESICARE TABLET, FILM COATED 10MG	VESICARE TABLET, FILM COATED 10MG	959/20T	ASTELLAS PHARMACEUTICALS A.E.B.E.	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)*
VESICARE TABLET, FILM	VESICARE TABLET, FILM	960/20T	ASTELLAS PHARMACEUTICALS A.E.B.E.	A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch

COATED 5MG	COATED 5MG			release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NIZORAL CREAM 2%	NIZORAL CREAM 2%	8940/23T	STADA ARZNEIMITTEL AG	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
ZITAMIN SOLUTION FOR INFUSION 2MG/ML	ZITAMIN SOLUTION FOR INFUSION 2MG/ML	7439/23T	NORIDEM ENTERPRISES LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZITAMIN SOLUTION FOR INJECTION 5MG/ML	ZITAMIN SOLUTION FOR INJECTION 5MG/ML	7437/23T	NORIDEM ENTERPRISES LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZITAMIN SOLUTION FOR INJECTION 7.5MG/ML	ZITAMIN SOLUTION FOR INJECTION 7.5MG/ML	7436/23T	NORIDEM ENTERPRISES LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZITAMIN SOLUTION FOR INJECTION 10MG/ML	ZITAMIN SOLUTION FOR INJECTION 10MG/ML	7435/23T	NORIDEM ENTERPRISES LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZITAMIN SOLUTION FOR INJECTION 2MG/ML	ZITAMIN SOLUTION FOR INJECTION 2MG/ML	7438/23T	NORIDEM ENTERPRISES LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products

				intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REMABIRAT TABLET, FILM COATED 500MG	REMABIRAT TABLET, FILM COATED 500MG	9018/23T, 9019/23T, 9020/23T, 9021/23T, 9022/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the B.I.a.3.b B.I.a.3.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc
REMABIRAT TABLET, FILM COATED 250MG	REMABIRAT TABLET, FILM COATED 250MG	9023/23T, 9024/23T, 9025/23T, 9026/23T, 9027/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the B.I.a.3.b B.I.a.3.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc

REMABIRAT TABLET, FILM COATED 1000MG	REMABIRAT TABLET, FILM COATED 1000MG	9013/23T, 9014/23T, 9015/23T, 9016/23T, 9017/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the B.I.a.3.b B.I.a.3.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc
TEMELOR SOLUTION FOR INJECTION 4MG/ML	TEMELOR SOLUTION FOR INJECTION 4MG/ML	228/23T, 229/23T, 230/23T, 231/23T, 232/23T	MEDOCHEMIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.1.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
PACLITAXEL ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXEL ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	8505/22T	ACCORD HEALTHCARE S.L.U	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
CANDESARTAN KRKA TABLET 32MG	CANDESARTAN KRKA TABLET 32MG	3368/23T	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
CANDESARTAN KRKA TABLET 8MG	CANDESARTAN KRKA TABLET 8MG	3370/23T	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
CANDESARTAN KRKA TABLET 16MG	CANDESARTAN KRKA TABLET 16MG	3369/23T	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
CANDESARTAN KRKA TABLET 4MG	CANDESARTAN KRKA TABLET 4MG	3371/23T	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
CANDESARTAN TAD TABLET 32MG	CANDESARTAN TAD TABLET 32MG	3586/23T	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 C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
CANDESARTAN TAD	CANDESARTAN TAD	3587/23T	TAD PHARMA GMBH	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

TABLET 16MG	TABLET 16MG			MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ULCEDINE FILM COATED TABLETS 20mg	ULCEDINE FILM COATED TABLETS 20mg	2468/21T	CODAL-SYNTO LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ULCEDINE FILM COATED TABLETS 40MG	ULCEDINE FILM COATED TABLETS 40MG	2469/21T	CODAL-SYNTO LIMITED	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
NOPRILAM DT POWDER FOR ORAL SUSPENSION (400MG/57 MG)/5ML	NOPRILAM DT POWDER FOR ORAL SUSPENSION (400MG/57 MG)/5ML	8935/23T, 8936/23T, 8937/23T	BIAL-PORTELA & CA, SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
AZACITIDINE/SANDOZ POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	AZACITIDINE/SANDOZ POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	6989/23T	SANDOZ PHARMACEUTICALS D.D.	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
ANAGRELIDE HYDROCHLORIDE CAPSULE, HARD 0.5MG	ANAGRELIDE HYDROCHLORIDE CAPSULE, HARD 0.5MG	6991/23T	SANDOZ GMBH	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
ABIRATERONE/SANDOZ TABLET, FILM COATED 500MG	ABIRATERONE/SANDOZ TABLET, FILM COATED 500MG	6990/23T	SANDOZ PHARMACEUTICALS D.D.	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
RIVAROXABAN/RAFARM TABLET, FILM COATED 10MG	RIVAROXABAN/RAFARM TABLET, FILM COATED 10MG	7452/23T	RAFARM S.A.	B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes
RIVAROXABAN/RAFA	RIVAROXABAN/RAFA	6825/23T	RAFARM S.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT -

RM TABLET, FILM COATED 15MG	RM TABLET, FILM COATED 15MG			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
RIVAROXABAN/RAFARM TABLET, FILM COATED 2.5MG	RIVAROXABAN/RAFARM TABLET, FILM COATED 2.5MG	6827/23T	RAFARM S.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
RIVAROXABAN/RAFARM TABLET, FILM COATED 10MG	RIVAROXABAN/RAFARM TABLET, FILM COATED 10MG	6826/23T	RAFARM S.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
RIVAROXABAN/RAFARM TABLET, FILM COATED 15MG AND 20MG	RIVAROXABAN/RAFARM TABLET, FILM COATED 15MG AND 20MG	6823/23T	RAFARM S.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
RIVAROXABAN/RAFARM TABLET, FILM COATED 20MG	RIVAROXABAN/RAFARM TABLET, FILM COATED 20MG	6824/23T	RAFARM S.A.	B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
AZACITIDINE/SANDOZ POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	AZACITIDINE/SANDOZ POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	562/23T	SANDOZ PHARMACEUTICALS D.D.	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
WELLBUTRIN XR MODIFIED-RELEASE TABLET 150MG	WELLBUTRIN XR MODIFIED-RELEASE TABLET 150MG	312/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
WELLBUTRIN XR MODIFIED-	WELLBUTRIN XR MODIFIED-	311/23T	GLAXOSMITHKLINE	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

RELEASE TABLET 300MG	RELEASE TABLET 300MG		(IRELAND) LIMITED	MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
WELLBUTRIN XR MODIFIED-RELEASE TABLET 150MG	WELLBUTRIN XR MODIFIED-RELEASE TABLET 150MG	4748/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
WELLBUTRIN XR MODIFIED-RELEASE TABLET 300MG	WELLBUTRIN XR MODIFIED-RELEASE TABLET 300MG	4747/23T	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
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	8216/23T, 8217/23T	SAPIENS PHARMACEUTICALS LTD	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	8218/23T, 8219/23T	SAPIENS PHARMACEUTICALS LTD	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability

				to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	1706/23T	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	1706/23T	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	1705/23T	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	1705/23T	SAPIENS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	1189/22T	BAUSCH + LOMB 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
LIPOCOMB CAPSULE, HARD 10MG/10MG	LIPOCOMB CAPSULE, HARD 10MG/10MG	6470/23T, 6471/23T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical,

			GYÓGYSZER GYÁR ZRT)	clinical or pharmacovigilance data A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
LIPOCOMB CAPSULE, HARD 20MG/10MG	LIPOCOMB CAPSULE, HARD 20MG/10MG	6468/23T, 6469/23T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
CLARIPEN GRANULES FOR ORAL SUSPENSION 250MG/5ML	CLARIPEN GRANULES FOR ORAL SUSPENSION 250MG/5ML	5270/22T, 5271/22T, 5272/22T, 5273/22T, 5274/22T, 5275/22T	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 C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
CO-DIOVAN TABLET, FILM COATED 80/12.5MG	CO-DIOVAN TABLET, FILM COATED 80/12.5MG	8179/23T	NOVARTIS IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
CO-DIOVAN TABLET, FILM COATED 160/25MG	CO-DIOVAN TABLET, FILM COATED 160/25MG	8177/23T	NOVARTIS IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
CO-DIOVAN TABLET, FILM COATED 160/12.5MG	CO-DIOVAN TABLET, FILM COATED 160/12.5MG	8178/23T	NOVARTIS IRELAND LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
DUOMAX TABLET, FILM COATED	DUOMAX TABLET, FILM COATED	8065/23T	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

500MG/150 MG	500MG/150 MG			an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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/0.01 MG/ML	DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01 MG/ML	323/23T	INIBSA DENTAL S.L.U.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005 MG/ML	DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005 MG/ML	322/23T	INIBSA DENTAL S.L.U.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
PNEUMOVAX 23 SOLUTION FOR INJECTION IN PREFILLED SYRINGE 25MCG/0.5 ML	PNEUMOVAX 23 SOLUTION FOR INJECTION IN PREFILLED SYRINGE 25MCG/0.5 ML	7974/23T	MERCK SHARP & DOHME BV	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
WILATE 1000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	WILATE 1000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	502/23T, 503/23T, 504/23T	OCTAPHARMA (IP) SPRL	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation 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 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
WILATE 500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	WILATE 500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	505/23T, 506/23T, 507/23T	OCTAPHARMA (IP) SPRL	B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation 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 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
PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	8733/23T	CODAL-SYNTO LIMITED	B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products
PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	8732/23T	CODAL-SYNTO LIMITED	B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products
FELDENE TABLET, DISPERSIBLE 20MG	FELDENE TABLET, DISPERSIBLE 20MG	3189/22T	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
TEKTROTYD KIT FOR RADIOPHARMACEUTICAL PREPARATION 20MCG	TEKTROTYD KIT FOR RADIOPHARMACEUTICAL PREPARATION 20MCG	7776/23T, 7777/23T	NARODOWE CENTRUM BADAN JADROWYCH	C.z C.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Other variation C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ACETAZOLAMIDE TABLET 250MG	ACETAZOLAMIDE TABLET 250MG	8858/23T	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

CARMUSTINE ACCORD POWDER & SOLVENT FOR CONCENTRATE FOR SOL.FOR INF. 100MG	CARMUSTINE ACCORD POWDER & SOLVENT FOR CONCENTRATE FOR SOL.FOR INF. 100MG	7899/23T	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
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 22.5MG	ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 22.5MG	6729/23T	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 7.5MG	ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 7.5MG	6730/23T	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 45MG	ELIGARD POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 45MG	6728/23T	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.P.A.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
VISPRING ADVANCE EYE DROPS, SOLUTION 0.5MG/ML	VISPRING ADVANCE EYE DROPS, SOLUTION 0.5MG/ML	6443/23T, 6444/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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
NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	NORDELOZ CONCENTRATE FOR SOLUTION FOR INFUSION 4MG/5ML	8121/23T	RAFARM S.A.	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MEDORPHAN SYRUP 1.5MG/ML	MEDORPHAN SYRUP 1.5MG/ML	5555/23T	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

MABRON SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	MABRON SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	8526/23T, 8527/23T	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.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)
ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 20MG	ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 20MG	7364/23T	KRKA D.D. NOVO MESTO	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
STRABEN LOZENGE 8.75MG	STRABEN LOZENGE 8.75MG	8458/23T	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
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+250)MCG/DOSE	ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+250)MCG/DOSE	4794/22T	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+500)MCG/DOSE	ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+500)MCG/DOSE	4793/22T	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
ROLENIUM INHALATION	ROLENIUM INHALATION	4795/22T	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

POWDER, PRE-DISPENSED (50+100)MCG/DOSE	POWDER, PRE-DISPENSED (50+100)MCG/DOSE			test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
RILCAPTON TABLET 50MG	RILCAPTON TABLET 50MG	8009/23T	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)
RILCAPTON TABLET 25MG	RILCAPTON TABLET 25MG	8008/23T	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)
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	7318/23T	SANOFI PASTEUR.	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
ABIRATERONE/SANDOZ TABLET, FILM COATED 500MG	ABIRATERONE/SANDOZ TABLET, FILM COATED 500MG	7098/23T	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
VAGIFEM FILM COATED VAGINAL TABLETS 10MCG	VAGIFEM FILM COATED VAGINAL TABLETS 10MCG	8253/23T	NOVO NORDISK A/S	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
NEBIVOLOL ACCORD TABLET 5MG	NEBIVOLOL ACCORD TABLET 5MG	2331/23T	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

NEBIVOLOL ACCORD TABLET 2.5MG	NEBIVOLOL ACCORD TABLET 2.5MG	2330/23T	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
NASOXYL NASAL SPRAY, SOLUTION 0.1%	NASOXYL NASAL SPRAY, SOLUTION 0.1%	8764/23T	SAPIENS PHARMACEUTICALS LTD	B.II.e.1.a.2 B.II.e.1.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms
HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	8105/23T, 8107/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer
HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	8104/23T, 8106/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer
VINBLASTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	VINBLASTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	8711/23T	PFIZER HELLAS AE	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
LEVOTHYROXINE ACCORD TABLET 100MCG	LEVOTHYROXINE ACCORD TABLET 100MCG	4255/23T	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 - Other variation
LEVOTHYROXINE ACCORD TABLET 25MCG	LEVOTHYROXINE ACCORD TABLET 25MCG	4257/23T	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 - Other variation
LEVOTHYROXINE ACCORD TABLET 50MCG	LEVOTHYROXINE ACCORD TABLET 50MCG	4256/23T	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 - Other variation
PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	8731/23T	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)
PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	8730/23T	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)
LAMISIL TABLET 250MG	LAMISIL TABLET 250MG	8746/23T	NOVARTIS IRELAND LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
LEXAVON EYE DROPS, SOLUTION 5MG/ML	LEXAVON EYE DROPS, SOLUTION 5MG/ML	7652/23T	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
MONTELUKAST ACCORD TABLET, CHEWABLE 5MG	MONTELUKAST ACCORD TABLET, CHEWABLE 5MG	7880/23T	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
MONTELUKAST ACCORD TABLET, CHEWABLE 4MG	MONTELUKAST ACCORD TABLET, CHEWABLE 4MG	7881/23T	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
DUCILTIA GASTRO-RESISTANT CAPSULE, HARD 60MG	DUCILTIA GASTRO-RESISTANT CAPSULE, HARD 60MG	1546/23T	PHARMATHEN 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
DUCILTIA GASTRO-RESISTANT CAPSULE, HARD 30MG	DUCILTIA GASTRO-RESISTANT CAPSULE, HARD 30MG	1547/23T	PHARMATHEN 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
ZYRTEC ORAL SOLUTION 0.1%	ZYRTEC ORAL SOLUTION 0.1%	1994/23T	UCB PHARMA SA	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
SPIRIVA RESPIMAT SOLUTION FOR INHALATION 2.5MCG/PUFF	SPIRIVA RESPIMAT SOLUTION FOR INHALATION 2.5MCG/PUFF	5958/22T	BOEHRINGER INGELHEIM INTERNATIONAL 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*
SPIRIVA INHALATION POWDER, HARD CAPSULE 18MCG	SPIRIVA INHALATION POWDER, HARD CAPSULE 18MCG	5955/22T	BOEHRINGER INGELHEIM INTERNATIONAL 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*
SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	5956/22T	BOEHRINGER INGELHEIM INTERNATIONAL 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*
STRIVERDI RESPIMAT SOLUTION FOR INHALATION	STRIVERDI RESPIMAT SOLUTION FOR INHALATION	5954/22T	BOEHRINGER INGELHEIM INTERNATIONAL 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*
SRIVASSO INHALATION POWDER, HARD CAPSULE 18MCG	SRIVASSO INHALATION POWDER, HARD CAPSULE 18MCG	5957/22T	BOEHRINGER INGELHEIM INTERNATIONAL 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*
YANIMO RESPIMAT SOLUTION FOR INHALATION	YANIMO RESPIMAT SOLUTION FOR INHALATION	5953/22T	BOEHRINGER INGELHEIM INTERNATIONAL 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*
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	6075/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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)
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR	VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR	6074/23T	GLAXOSMITHKLINE BIOLOGICALS SA	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)

INJECTION 2000PFU	INJECTION 2000PFU			
COZAAR TABLET, FILM COATED 12.5MG	COZAAR TABLET, FILM COATED 12.5MG	901/23T, 902/23T, 903/23T	N.V. ORGANON	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
COZAAR TABLET, FILM COATED 50MG	COZAAR TABLET, FILM COATED 50MG	898/23T, 899/23T, 900/23T	N.V. ORGANON	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
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	5898/23T	GLAXOSMITH KLINE BIOLOGICALS SA	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	5898/23T	GLAXOSMITH KLINE BIOLOGICALS SA	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	4875/23T, 4876/23T	GLAXOSMITH KLINE 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 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
PRIORIX-TETRA	PRIORIX-TETRA	4877/23T, 4878/23T	GLAXOSMITH KLINE	B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE -

POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE		BIOLOGICALS SA	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
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	7440/23T, 7441/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.e.3.z B.II.e.3.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Other variation B.II.c.2.z B.II.c.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other variation
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	7442/23T, 7443/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.e.3.z B.II.e.3.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - Other variation B.II.c.2.z B.II.c.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other variation
IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	4815/23T	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)*
IDARUBICIN ACCORD SOLUTION FOR INJECTION 10MG/10ML	IDARUBICIN ACCORD SOLUTION FOR INJECTION 10MG/10ML	4814/23T	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)*
IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	4813/23T	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)*
PANADOL ADVANCE TABLET, FILM COATED 500MG	PANADOL ADVANCE TABLET, FILM COATED 500MG	8620/23T, 8621/23T, 8622/23T, 8623/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
LEVETIRACETAM NORIDEM CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	LEVETIRACETAM NORIDEM CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/ML	8175/23T	NORIDEM ENTERPRISES 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)*
MEDICINAL NITROUS OXIDE LINDE HADJIKYRIAKOS GAS LTD MEDICINAL GAS, LIQUEFIED 100%	MEDICINAL NITROUS OXIDE LINDE HADJIKYRIAKOS GAS LTD MEDICINAL GAS, LIQUEFIED 100%	8753/23T	LINDE HADJIKYRIAKOS GAS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 6000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 6000IU	5116/23T, 5117/23T	VENIPHARM	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	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED	5112/23T, 5113/23T	VENIPHARM	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

SYRINGE 10000IU	SYRINGE 10000IU			product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 2000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 2000IU	5110/23T, 5111/23T	VENIPHARM	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 SYRINGE 4000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 4000IU	5108/23T, 5109/23T	VENIPHARM	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 SYRINGE 8000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 8000IU	5114/23T, 5115/23T	VENIPHARM	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
PRODUOD OPA SOLUTION FOR INFUSION (240MG+12 MG)/ML	PRODUOD OPA SOLUTION FOR INFUSION (240MG+12 MG)/ML	7444/23T	ABBVIE PHARMACEU TICALS 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
XYZAL ORAL SOLUTION 0.5MG/ML	XYZAL ORAL SOLUTION 0.5MG/ML	7799/23T	UCB PHARMA SA	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 50MG/ML	INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 50MG/ML	5538/23T	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
EZETROL TABLET 10MG	EZETROL TABLET 10MG	7755/23T, 7756/23T	N.V. ORGANON	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
INEGY TABLET 10MG/10MG	INEGY TABLET 10MG/10MG	7753/23T, 7754/23T	N.V. ORGANON	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
INEGY TABLET 10MG/20MG	INEGY TABLET 10MG/20MG	7751/23T, 7752/23T	N.V. ORGANON	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
INEGY TABLET 10MG/80MG	INEGY TABLET 10MG/80MG	7747/23T, 7748/23T	N.V. ORGANON	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
LIPTRUZET TABLET, FILM COATED 10MG/40MG	LIPTRUZET TABLET, FILM COATED 10MG/40MG	7761/23T, 7762/23T	N.V. ORGANON	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
LIPTRUZET TABLET, FILM COATED 10MG/80MG	LIPTRUZET TABLET, FILM COATED 10MG/80MG	7763/23T, 7764/23T	N.V. ORGANON	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
LIPTRUZET TABLET, FILM COATED 10MG/10MG	LIPTRUZET TABLET, FILM COATED 10MG/10MG	7757/23T, 7758/23T	N.V. ORGANON	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
INEGY TABLET 10MG/40MG	INEGY TABLET 10MG/40MG	7749/23T, 7750/23T	N.V. ORGANON	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
LIPTRUZET TABLET, FILM COATED 10MG/20MG	LIPTRUZET TABLET, FILM COATED 10MG/20MG	7759/23T, 7760/23T	N.V. ORGANON	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
IDARUBICIN ACCORD SOLUTION FOR	IDARUBICIN ACCORD SOLUTION FOR	5027/23T	ACCORD HEALTHCARE S.L.U	B.II.e.3.b B.II.e.3.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate

INJECTION 10MG/10ML	INJECTION 10MG/10ML			packaging of the finished product - Other changes to a test procedure (including replacement or addition)
IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	IDARUBICIN ACCORD SOLUTION FOR INJECTION 20MG/20ML	5026/23T	ACCORD HEALTHCARE S.L.U	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)
IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	IDARUBICIN ACCORD SOLUTION FOR INJECTION 5MG/5ML	5028/23T	ACCORD HEALTHCARE S.L.U	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)
LIPTRUZET TABLET, FILM COATED 10MG/40MG	LIPTRUZET TABLET, FILM COATED 10MG/40MG	5281/23T	N.V. ORGANON	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
LIPTRUZET TABLET, FILM COATED 10MG/80MG	LIPTRUZET TABLET, FILM COATED 10MG/80MG	5280/23T	N.V. ORGANON	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
LIPTRUZET TABLET, FILM COATED 10MG/20MG	LIPTRUZET TABLET, FILM COATED 10MG/20MG	5282/23T	N.V. ORGANON	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
LIPTRUZET TABLET, FILM COATED 10MG/10MG	LIPTRUZET TABLET, FILM COATED 10MG/10MG	5283/23T	N.V. ORGANON	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
IMODIUM ORIGINAL CAPSULE, HARD 2MG	IMODIUM ORIGINAL CAPSULE, HARD 2MG	8697/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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
TREBON-N POWDER FOR ORAL SUSPENSION 200MG/5ML	TREBON-N POWDER FOR ORAL SUSPENSION 200MG/5ML	7651/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
SPIRIVA INHALATION POWDER, HARD	SPIRIVA INHALATION POWDER, HARD	6777/22T, 6778/22T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

CAPSULE 18MCG	CAPSULE 18MCG			B.IV.z B.IV.z - QUALITY CHANGES - Medical Devices - Other variation
SRIVASSO INHALATIO N POWDER, HARD CAPSULE 18MCG	SRIVASSO INHALATIO N POWDER, HARD CAPSULE 18MCG	6779/22T , 6780/22T	BOEHRINGER INGELHEIM INTERNATION AL GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.IV.z B.IV.z - QUALITY CHANGES - Medical Devices - Other variation
TENORMIN TABLET, FILM COATED 50MG	TENORMIN TABLET, FILM COATED 50MG	2969/23T, 2970/23T, 2971/23T, 2972/23T, 2973/23T, 2974/23T, 2975/23T, 2976/23T	ATNAHS PHARMA NETHERLAND S B.V.	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements 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.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ran B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finishe 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 suita
TENORMIN TABLET, FILM COATED 25MG	TENORMIN TABLET, FILM COATED 25MG	2977/23T, 2978/23T, 2979/23T, 2980/23T, 2981/23T, 2982/23T, 2983/23T, 2984/23T	ATNAHS PHARMA NETHERLAND S B.V.	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements 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.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ran B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finishe 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 suita
TENORMIN TABLET, FILM COATED 100MG	TENORMIN TABLET, FILM COATED 100MG	2961/23T, 2962/23T, 2963/23T, 2964/23T, 2965/23T, 2966/23T, 2967/23T, 2968/23T	ATNAHS PHARMA NETHERLANDS B.V.	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ran B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finishe 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 suita
CEFUROXIME VENUS PHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 1500MG	CEFUROXIME VENUS PHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 1500MG	4667/23T	VENUS PHARMA GMBH	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
CEFUROXIME VENUS PHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG	CEFUROXIME VENUS PHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG	4668/23T	VENUS PHARMA GMBH	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ANAFRANIL TABLET, COATED 25MG	ANAFRANIL TABLET, COATED 25MG	8047/23T, 8048/23T	PHARMAAND GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ANAFRANIL SLOW RELEASE	ANAFRANIL SLOW RELEASE	8045/23T, 8046/23T	PHARMAAND GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name

TABLETS DIVIDABLE 75MG	TABLETS DIVIDABLE 75MG			and/or address of the marketing authorisation holder
ANAFRANIL TABLET, COATED 10MG	ANAFRANIL TABLET, COATED 10MG	8049/23T, 8050/23T	PHARMAAND GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CHORIOMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	CHORIOMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	8589/23T	IBSA FARMACEUTICI ITALIA SRL	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
EFEXOR XR PROLONGED RELEASE CAPSULES 37.5MG	EFEXOR XR PROLONGED RELEASE CAPSULES 37.5MG	4254/23T	VIATRIS HELLAS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 75MG	4253/23T	VIATRIS HELLAS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	EFEXOR XR CAPSULE, HARD, PROLONGED-RELEASE 150MG	4252/23T	VIATRIS HELLAS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ATORVASTATIN GENERICS TABLET, FILM COATED 20MG	ATORVASTATIN GENERICS TABLET, FILM COATED 20MG	3861/23T, 3862/23T, 3863/23T, 3864/23T	GENERICS PHARMA HELLAS LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE -

				Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance o
ATORVASTATIN GENERICS TABLET, FILM COATED 10MG	ATORVASTATIN GENERICS TABLET, FILM COATED 10MG	3865/23T, 3866/23T, 3867/23T, 3868/23T	GENERICS PHARMA HELLAS LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance o
ATORVASTATIN GENERICS TABLET, FILM COATED 40MG	ATORVASTATIN GENERICS TABLET, FILM COATED 40MG	3857/23T, 3858/23T, 3859/23T, 3860/23T	GENERICS PHARMA HELLAS LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance o

ATORVASTATIN GENERICS TABLET, FILM COATED 10MG	ATORVASTATIN GENERICS TABLET, FILM COATED 10MG	6931/23T, 6932/23T	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 20MG	ATORVASTATIN GENERICS TABLET, FILM COATED 20MG	6929/23T, 6930/23T	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	ATORVASTATIN GENERICS TABLET, FILM COATED 40MG	6927/23T, 6928/23T	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
COSYREL TABLET, FILM COATED 5MG/10MG	COSYREL TABLET, FILM COATED 5MG/10MG	8790/22T	LES LABORATOIRES SERVIER	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
COSYREL TABLET, FILM COATED 5MG/5MG	COSYREL TABLET, FILM COATED 5MG/5MG	8789/22T	LES LABORATOIRES SERVIER	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
COSYREL TABLET, FILM COATED 10MG/10MG	COSYREL TABLET, FILM COATED 10MG/10MG	8792/22T	LES LABORATOIRES SERVIER	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
COSYREL TABLET, FILM COATED 10MG/5MG	COSYREL TABLET, FILM COATED 10MG/5MG	8791/22T	LES LABORATOIRES SERVIER	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND 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 OR INFUSION 4MG/ML	DEXAMETHASONE/KABI SOLUTION FOR INJECTION OR INFUSION 4MG/ML	3254/22T	FRESENIUS KABI HELLAS A.E.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority, e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH.
ROSU-ASA CAPSULE, HARD 5MG/100MG	ROSU-ASA CAPSULE, HARD 5MG/100MG	2560/23T	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ROSU-ASA CAPSULE, HARD 20MG/100MG	ROSU-ASA CAPSULE, HARD 20MG/100MG	2558/23T	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ROSU-ASA CAPSULE, HARD 10MG/100MG	ROSU-ASA CAPSULE, HARD 10MG/100MG	2559/23T	IASIS PHARMACEUTICALS HELLAS SA	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	8347/23T	ALTAN PHARMACEUTICALS S.A.	B.II.f.1.e B.II.f.1.e - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change to an approved stability protocol
PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	8521/23T	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
PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	8520/23T	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
MEDOCIPRIN TABLET, FILM COATED 500MG	MEDOCIPRIN TABLET, FILM COATED 500MG	8575/23T	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
MEDOCIPRIN TABLET, FILM COATED 250MG	MEDOCIPRIN TABLET, FILM COATED 250MG	8576/23T	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
AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOOD UNITS	7453/23T, 7454/23T, 7455/23T, 7456/23T	IPSEN PHARMA	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.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.a.4.b B.I.a.4.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Addition of a new in-process test and limits
REMODULIN SOLUTION FOR INFUSION 2.5MG/ML	REMODULIN SOLUTION FOR INFUSION 2.5MG/ML	5428/23T	FERRER INTERNACIONAL 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
REMODULIN SOLUTION FOR INFUSION 10MG/ML	REMODULIN SOLUTION FOR INFUSION 10MG/ML	5427/23T	FERRER INTERNACIONAL 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
REMODULIN SOLUTION FOR	REMODULIN SOLUTION FOR	5430/23T	FERRER INTERNACIONAL 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

INFUSION 5MG/ML	INFUSION 5MG/ML			product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate
REMODULIN SOLUTION FOR INFUSION 1MG/ML	REMODULIN SOLUTION FOR INFUSION 1MG/ML	5429/23T	FERRER INTERNACIONAL 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
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	7795/23T, 7796/23T, 7797/23T, 7798/23T	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 product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder 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*
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	7731/23T	SANOFI PASTEUR.	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
APLERIA TABLET, FILM COATED 25MG	APLERIA TABLET, FILM COATED 25MG	6448/23T	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
APLERIA TABLET, FILM COATED 50MG	APLERIA TABLET, FILM COATED 50MG	6447/23T	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

ARCOXIA TABLET, FILM COATED 90MG	ARCOXIA TABLET, FILM COATED 90MG	7014/23T, 7015/23T, 7016/23T, 7017/23T, 7018/23T	N.V. ORGANON	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.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
ARCOXIA TABLET, FILM COATED 120MG	ARCOXIA TABLET, FILM COATED 120MG	7004/23T, 7005/23T, 7006/23T, 7007/23T, 7008/23T	N.V. ORGANON	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.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
ARCOXIA TABLET, FILM COATED 60MG	ARCOXIA TABLET, FILM COATED 60MG	7009/23T, 7010/23T, 7011/23T, 7012/23T, 7013/23T	N.V. ORGANON	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.e.4.a B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.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
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	ALBUREX 20 SOLUTION FOR INFUSION 200G/L	6959/23T	CSL BEHRING GMBH	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
NEFILIN MODIFIED-RELEASE TABLET 6MG/0.4MG	NEFILIN MODIFIED-RELEASE TABLET 6MG/0.4MG	7379/23T, 7380/23T	ELPEN PHARMACEUTICAL CO INC	B.III.2.a.2 B.III.2.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/active substance starting material
AVELOX TABLET, FILM COATED 400MG	AVELOX TABLET, FILM COATED 400MG	6314/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CARBOPLATIN/HOSPIRA SOLUTION FOR INFUSION 10MG/ML	CARBOPLATIN/HOSPIRA SOLUTION FOR INFUSION 10MG/ML	3321/23T	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 C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYNORM SOLUTION FOR INJECTION OR INFUSION 10MG/ML	OXYNORM SOLUTION FOR INJECTION OR INFUSION 10MG/ML	8562/23T	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

OXYNORM SOLUTION FOR INJECTION OR INFUSION 50MG/ML	OXYNORM SOLUTION FOR INJECTION OR INFUSION 50MG/ML	8563/23T	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MONTOL TABLET, CHEWABLE 5MG	MONTOL TABLET, CHEWABLE 5MG	8558/23T	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
MONTOL TABLET, FILM COATED 10MG	MONTOL TABLET, FILM COATED 10MG	8557/23T	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
MONTOL TABLET, CHEWABLE 4MG	MONTOL TABLET, CHEWABLE 4MG	8559/23T	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
APONIL TABLET 100MG	APONIL TABLET 100MG	8535/23T	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
FLEXBUMIN SOLUTION FOR	FLEXBUMIN SOLUTION FOR	7785/23T	BAXALTA INNOVATIONS 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

INFUSION 200G/L	INFUSION 200G/L			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)
FLEXBUMIN SOLUTION FOR INFUSION 250G/L	FLEXBUMIN SOLUTION FOR INFUSION 250G/L	7784/23T	BAXALTA INNOVATIONS 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 flavouring material)
NEPHROTECT SOLUTION FOR INFUSION 10%	NEPHROTECT SOLUTION FOR INFUSION 10%	7858/23T, 7859/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
CREON 10000 CAPSULE, HARD 150MG	CREON 10000 CAPSULE, HARD 150MG	3723/23T	VIATRIS HEALTHCARE LIMITED.	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product
CREON 10000 CAPSULE, HARD 150MG	CREON 10000 CAPSULE, HARD 150MG	3723/23T	VIATRIS HEALTHCARE LIMITED.	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product
CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	3725/23T	VIATRIS HEALTHCARE LIMITED.	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active

				substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product
CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	3725/23T	VIATRIS HEALTHCARE LIMITED.	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	3724/23T	VIATRIS HEALTHCARE LIMITED.	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	3724/23T	VIATRIS HEALTHCARE LIMITED.	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product
DULSEVIA GASTRO-RESISTANT CAPSULE, HARD 60MG	DULSEVIA GASTRO-RESISTANT CAPSULE, HARD 60MG	7715/23T	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
DULSEVIA GASTRO-	DULSEVIA GASTRO-	7716/23T	TAD PHARMA GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS

RESISTANT CAPSULE, HARD 30MG	RESISTANT CAPSULE, HARD 30MG			- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DULSEVIA GASTRO-RESISTANT CAPSULE, HARD 60MG	DULSEVIA GASTRO-RESISTANT CAPSULE, HARD 60MG	7720/23T	TAD PHARMA GMBH	Type IA, B.III.1.a.2 Submission of a new or updated Ph. Eur. certificate of suitability
DULSEVIA GASTRO-RESISTANT CAPSULE, HARD 30MG	DULSEVIA GASTRO-RESISTANT CAPSULE, HARD 30MG	7721/23T	TAD PHARMA GMBH	Type IA, B.III.1.a.2 Submission of a new or updated Ph. Eur. certificate of suitability
GLUCAGEN HYPOKIT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1MG	GLUCAGEN HYPOKIT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1MG	7403/23T	NOVO NORDISK A/S	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol.
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 10MG/1.5ML	7401/23T	NOVO NORDISK A/S	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol.
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 15MG/1.5ML	7402/23T	NOVO NORDISK A/S	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	NORDITROPIN FLEXPRO SOLUTION FOR INJECTION IN A PRE-FILLED PEN 5MG/1.5ML	7400/23T	NOVO NORDISK A/S	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PANADOL COLD AND FLU	PANADOL COLD AND FLU	3588/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙ	C.I.3 a) Implementation of wording agreed by the competent authority

TABLET, FILM COATED	TABLET, FILM COATED		ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	
TRIPAN TABLET, FILM COATED 20MG	TRIPAN TABLET, FILM COATED 20MG	8400/23T	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
TRIPAN TABLET, FILM COATED 5MG	TRIPAN TABLET, FILM COATED 5MG	8401/23T	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
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	6285/20T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.1 Change in the name and/or address of the marketing authorisation holder
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	9889/22T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
COVERAM TABLET 5MG/5MG	COVERAM TABLET 5MG/5MG	5694/22T	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
COVERAM TABLET 10MG/5MG	COVERAM TABLET 10MG/5MG	5696/22T	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
COVERAM TABLET 5MG/10MG	COVERAM TABLET 5MG/10MG	5695/22T	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
COVERAM TABLET 10MG/10MG	COVERAM TABLET 10MG/10MG	5697/22T	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
COVERAM TABLET 10MG/5MG	COVERAM TABLET 10MG/5MG	7037/21T	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
COSYREL TABLET, FILM COATED 5MG/5MG	COSYREL TABLET, FILM COATED 5MG/5MG	7033/21T	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
COVERAM TABLET 5MG/5MG	COVERAM TABLET 5MG/5MG	7035/21T	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
COVERAM TABLET 10MG/10MG	COVERAM TABLET 10MG/10MG	7038/21T	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
COSYREL TABLET, FILM COATED 10MG/5MG	COSYREL TABLET, FILM COATED 10MG/5MG	7032/21T	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
COSYREL TABLET, FILM COATED 5MG/10MG	COSYREL TABLET, FILM COATED 5MG/10MG	7031/21T	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
COSYREL TABLET, FILM COATED 10MG/10MG	COSYREL TABLET, FILM COATED 10MG/10MG	7034/21T	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
VIACORAM TABLET 7MG/5MG	VIACORAM TABLET 7MG/5MG	7030/21T	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
VIACORAM TABLET 3.5MG/2.5MG	VIACORAM TABLET 3.5MG/2.5MG	7029/21T	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
COVERAM TABLET 5MG/10MG	COVERAM TABLET 5MG/10MG	7036/21T	LES LABORATOIRES SERVIER	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	3089/21T, 3090/21T, 3091/21T, 3092/21T, 3093/21T, 3094/21T, 3095/21T, 3096/21T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	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 - B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin B.II.e.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 qu B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished produc B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used
LIPREN TABLET, FILM COATED 10MG	LIPREN TABLET, FILM COATED 10MG	7559/23T, 7560/23T	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)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIPREN TABLET, FILM COATED 20MG	LIPREN TABLET, FILM COATED 20MG	7557/23T, 7558/23T	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)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS

				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIPREN TABLET, FILM COATED 40MG	LIPREN TABLET, FILM COATED 40MG	7555/23T, 7556/23T	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)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 1.5MG	DEXAMED TABLET 1.5MG	6426/23T	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
DEXAMED TABLET 0.5MG	DEXAMED TABLET 0.5MG	6427/23T	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 1G/VIAL	ZEPILEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	8286/23T	MEDOCHEMIE LTD	B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that affects the product information

ZEPILEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	ZEPILEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	8285/23T	MEDOCHEMIE LTD	B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that affects the product information
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	7200/23T, 7201/23T, 7202/23T, 7203/23T	CSL BEHRING GMBH	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.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
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	7196/23T, 7197/23T, 7198/23T, 7199/23T	CSL BEHRING GMBH	B.II.b.5.a B.II.b.5.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.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
ACICLOVIR ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	ACICLOVIR ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	7568/23T	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
DUROGESIC PATCH, TRANSDERMAL 100MCG/H	DUROGESIC PATCH, TRANSDERMAL 100MCG/H	2806/23T	JANSSEN-CILAG INTERNATIONAL NV	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
DUROGESIC PATCH, TRANSDERMAL 25MCG/H	DUROGESIC PATCH, TRANSDERMAL 25MCG/H	2808/23T	JANSSEN-CILAG INTERNATIONAL NV	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
DUROGESIC PATCH, TRANSDERMAL 50MCG/H	DUROGESIC PATCH, TRANSDERMAL 50MCG/H	2807/23T	JANSSEN-CILAG INTERNATIONAL NV	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
DASATINIB PHARMASCIENCE TABLET, FILM COATED 80MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 80MG	6976/22T, 6977/22T	PHARMASCIENCE INTERNATIONAL LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code 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
DASATINIB PHARMASCIENCE TABLET, FILM COATED 100MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 100MG	6974/22T, 6975/22T	PHARMASCIENCE INTERNATIONAL LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code 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
DASATINIB PHARMASCIENCE TABLET, FILM COATED 50MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 50MG	6980/22T, 6981/22T	PHARMASCIENCE INTERNATIONAL LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code 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
DASATINIB PHARMASCIENCE TABLET, FILM COATED 140MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 140MG	6972/22T, 6973/22T	PHARMASCIENCE INTERNATIONAL LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code 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
DASATINIB PHARMASCIENCE TABLET, FILM COATED 70MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 70MG	6978/22T, 6979/22T	PHARMASCIENCE INTERNATIONAL LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code 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
DASATINIB PHARMASCIENCE TABLET, FILM COATED 20MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 20MG	6982/22T, 6983/22T	PHARMASCIENCE INTERNATIONAL LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code 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
DASATINIB PHARMASCIENCE TABLET, FILM COATED 80MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 80MG	8159/22T	PHARMASCIENCE INTERNATIONAL LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
DASATINIB PHARMASCIENCE TABLET, FILM COATED 100MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 100MG	8158/22T	PHARMASCIENCE INTERNATIONAL LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
DASATINIB PHARMASCIENCE TABLET, FILM COATED 50MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 50MG	8161/22T	PHARMASCIENCE INTERNATIONAL LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
DASATINIB PHARMASCIENCE TABLET, FILM COATED 140MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 140MG	8157/22T	PHARMASCIENCE INTERNATIONAL LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
DASATINIB PHARMASCIENCE TABLET, FILM COATED 70MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 70MG	8160/22T	PHARMASCIENCE INTERNATIONAL LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
DASATINIB PHARMASCIENCE TABLET, FILM COATED 20MG	DASATINIB PHARMASCIENCE TABLET, FILM COATED 20MG	8162/22T	PHARMASCIENCE INTERNATIONAL LTD	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation

DUOKOPT EYE DROPS, SOLUTION 20MG/ML+ 5MG/ML	DUOKOPT EYE DROPS, SOLUTION 20MG/ML+ 5MG/ML	5967/23T, 5968/23T, 5969/23T	LABORATOIR ES THEA	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 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
ETOPOSID E ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 20MG/ML	ETOPOSID E ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 20MG/ML	7883/23T	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
MABRON SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	MABRON SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	5649/23T	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
CEFUROXI ME-SYNTO TABLET, FILM COATED 250MG	CEFUROXI ME-SYNTO TABLET, FILM COATED 250MG	7574/23T	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
CEFUROXI ME-SYNTO TABLET, FILM COATED 500MG	CEFUROXI ME-SYNTO TABLET, FILM COATED 500MG	7573/23T	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

CEFUROXIME-SYNTO POWDER FOR INJECTION 1.5G	CEFUROXIME-SYNTO POWDER FOR INJECTION 1.5G	7547/23T, 7548/23T, 7549/23T, 7550/23T, 7551/23T, 7552/23T, 7553/23T, 7554/23T	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
CEFUROXIME-SYNTO POWDER FOR INJECTION 750MG/VIAL	CEFUROXIME-SYNTO POWDER FOR INJECTION 750MG/VIAL	7539/23T, 7540/23T, 7541/23T, 7542/23T, 7543/23T, 7544/23T, 7545/23T, 7546/23T	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
LEFLON TABLET, FILM COATED 15MG	LEFLON TABLET, FILM COATED 15MG	2548/23T	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
LEFLON TABLET, FILM COATED 20MG	LEFLON TABLET, FILM COATED 20MG	2547/23T	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
LEFLON TABLET, FILM COATED 10MG	LEFLON TABLET, FILM COATED 10MG	2549/23T	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
LEFLON TABLET, FILM COATED 100MG	LEFLON TABLET, FILM COATED 100MG	2546/23T	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
SYNTOCEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	SYNTOCEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	8510/23T, 8511/23T, 8512/23T	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
TORVACA RD NEO TABLET, FILM COATED 40MG	TORVACA RD NEO TABLET, FILM COATED 40MG	7301/23T	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TORVACA RD NEO TABLET, FILM COATED 20MG	TORVACA RD NEO TABLET, FILM COATED 20MG	7302/23T	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TORVACA RD NEO TABLET, FILM COATED 10MG	TORVACA RD NEO TABLET, FILM COATED 10MG	7303/23T	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TORVACA RD NEO TABLET, FILM COATED 20MG	TORVACA RD NEO TABLET, FILM COATED 20MG	2034/23T, 2035/23T, 2036/23T	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 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 - Eur
TORVACARD NEO TABLET, FILM COATED 40MG	TORVACARD NEO TABLET, FILM COATED 40MG	2031/23T, 2032/23T, 2033/23T	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 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 - Eur
TORVACARD NEO TABLET, FILM COATED 10MG	TORVACARD NEO TABLET, FILM COATED 10MG	2037/23T, 2038/23T, 2039/23T	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 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 - Eur
APOTEL COLD & FLU DAY & NIGHT EFFERVES	APOTEL COLD & FLU DAY & NIGHT EFFERVES	8026/23T, 8027/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.3.z C.I.3.z - SAFETY, EFFICACY,

CENT TABLET	CENT TABLET		LABORATORIES SA	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure 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
ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	7305/23T	SANDOZ GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	7304/23T	SANDOZ GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	7306/23T	SANDOZ GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FINASTERIDE ACCORD TABLET, FILM COATED 5MG	FINASTERIDE ACCORD TABLET, FILM COATED 5MG	6415/23T	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
FINASTERIDE ACCORD TABLET, FILM COATED 1MG	FINASTERIDE ACCORD TABLET, FILM COATED 1MG	6416/23T	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

DEXATON ORAL SOLUTION 2MG/5ML	DEXATON ORAL SOLUTION 2MG/5ML	7771/23T	VIANEX S.A	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BOSENTAN AUROBINDO TABLET, FILM COATED 62.5MG	BOSENTAN AUROBINDO TABLET, FILM COATED 62.5MG	4678/23T	AUROBINDO PHARMA (MALTA) LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation
BOSENTAN AUROBINDO TABLET, FILM COATED 125MG	BOSENTAN AUROBINDO TABLET, FILM COATED 125MG	4677/23T	AUROBINDO PHARMA (MALTA) LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation
DELTIUS CAPSULE, HARD 50000IU	DELTIUS CAPSULE, HARD 50000IU	8647/23T, 8648/23T, 8649/23T, 8650/23T, 8651/23T, 8652/23T, 8653/23T	ITF HELLAS A.E.	B.III.1 a) 2. Updated certificate from an already approved manufacturer B.III.1 b) 3. Updated certificate from an already approved manufacturer B.III.1 b) 4. Deletion of certificates (in case multiple certificates exist per material)
DELTIUS CAPSULE, HARD 25000IU	DELTIUS CAPSULE, HARD 25000IU	8654/23T, 8655/23T, 8656/23T, 8657/23T, 8658/23T, 8659/23T, 8660/23T	ITF HELLAS A.E.	B.III.1 a) 2. Updated certificate from an already approved manufacturer B.III.1 b) 3. Updated certificate from an already approved manufacturer B.III.1 b) 4. Deletion of certificates (in case multiple certificates exist per material)
ASPIRIN EC TABLET, GASTRO-RESISTANT 100MG	ASPIRIN EC TABLET, GASTRO-RESISTANT 100MG	10245/20T	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
SPIRIVA RESPIMAT SOLUTION FOR INHALATION 2.5MCG/PUFF	SPIRIVA RESPIMAT SOLUTION FOR INHALATION 2.5MCG/PUFF	7717/23T	BOEHRINGER INGELHEIM INTERNATIONAL 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
SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	7718/23T	BOEHRINGER INGELHEIM INTERNATIONAL 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
YANIMO RESPIMAT SOLUTION FOR INHALATION	YANIMO RESPIMAT SOLUTION FOR INHALATION	7719/23T	BOEHRINGER INGELHEIM INTERNATIONAL 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
TRIATEC PLUS TABLET 5MG/25MG	TRIATEC PLUS TABLET 5MG/25MG	4882/23T	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
TRIATEC PLUS TABLET 5MG/25MG	TRIATEC PLUS TABLET 5MG/25MG	9635/21T	SANOFI WINTHROP INDUSTRIE.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
VINBLASTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	VINBLASTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	8574/23T	PFIZER HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TRIOFAN FOR ADULTS NASAL SPRAY (1+10)MG	TRIOFAN FOR ADULTS NASAL SPRAY (1+10)MG	8196/23T	THE STAR MEDICINES IMPORTERS CO. LTD	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
TRIOFAN FOR CHILDREN NASAL SPRAY (0.5+5)MG	TRIOFAN FOR CHILDREN NASAL SPRAY (0.5+5)MG	8195/23T	THE STAR MEDICINES IMPORTERS CO. LTD	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range
SMOFLIPID EMULSION FOR INFUSION 20%	SMOFLIPID EMULSION FOR INFUSION 20%	7073/23T	FRESENIUS KABI HELLAS A.E.	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
KIVALA TABLET, FILM COATED	KIVALA TABLET, FILM COATED	8547/23T	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)*
PARACETAMOL ACCORD SOLUTION FOR INFUSION 10MG/ML	PARACETAMOL ACCORD SOLUTION FOR INFUSION 10MG/ML	7714/23T	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)

ETOPOSIDE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	ETOPOSIDE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	2024/22T	ACCORD HEALTHCARE S.L.U	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)
OLOXICAM SOLUTION FOR INJECTION 10MG/ML	OLOXICAM SOLUTION FOR INJECTION 10MG/ML	8552/23T	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
OLOXICAM TABLET 15MG	OLOXICAM TABLET 15MG	8538/23T	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
BENCET MOUTH SPRAY OROMUCOSAL SPRAY, SOLUTION (0.15 + 0.5)% w/v	BENCET MOUTH SPRAY OROMUCOSAL SPRAY, SOLUTION (0.15 + 0.5)% w/v	8485/23T	NASSINGTON LTD	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
SYMBICORT PRESSURISED INHALATION, SUSPENSION 80MCG/2.25MCG/ACTUATION	SYMBICORT PRESSURISED INHALATION, SUSPENSION 80MCG/2.25MCG/ACTUATION	6868/23T, 6869/23T	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 used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.I.a.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
SYMBICORT PRESSURISED INHALATION, SUSPENSION 160/4.5MCG/ACTUATION	SYMBICORT PRESSURISED INHALATION, SUSPENSION 160/4.5MCG/ACTUATION	6870/23T, 6871/23T	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 used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) B.I.a.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
ROSAZIMIB TABLET, FILM COATED 20MG/10MG	ROSAZIMIB TABLET, FILM COATED 20MG/10MG	2437/23T	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
ROSAZIMIB TABLET, FILM COATED 5MG/10MG	ROSAZIMIB TABLET, FILM COATED 5MG/10MG	2436/23T	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
ROSAZIMIB TABLET, FILM COATED 10MG/10MG	ROSAZIMIB TABLET, FILM COATED 10MG/10MG	2438/23T	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
LAMISIL ONCE CUTANEOUS SOLUTION 1%	LAMISIL ONCE CUTANEOUS SOLUTION 1%	8408/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
LAMISIL CREAM 1%	LAMISIL CREAM 1%	8409/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
MEDORIL CAPSULE, HARD 500MG	MEDORIL CAPSULE, HARD 500MG	4232/23T	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
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.3MG/ML	BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.3MG/ML	6557/22T	PHARMATHEN S.A.	B.I.z B.I.z - Quality change - Active substance - Other variation
BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.1MG/ML	BIMATOPROST/PHARMATHEN EYE DROPS, SOLUTION 0.1MG/ML	6558/22T	PHARMATHEN S.A.	B.I.z B.I.z - Quality change - Active substance - Other variation
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 200MCG	MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 200MCG	8529/23T	NOVARTIS IRELAND LIMITED	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer

MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 400MCG	MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 400MCG	8528/23T	NOVARTIS IRELAND LIMITED	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer
RINGER LACTATE/BAXTER(VIAFLO) SOLUTION FOR INFUSION	RINGER LACTATE/BAXTER(VIAFLO) SOLUTION FOR INFUSION	4929/23T	BAXTER (HELLAS) EPE	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
PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG	PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG	7261/23T, 7262/23T, 7263/23T, 7264/23T, 7265/23T, 7266/23T, 7267/23T, 7268/23T, 7269/23T	MEDOCHEMIE 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 manufacturi B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specificatio 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 /
PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	7252/23T, 7253/23T, 7254/23T, 7255/23T, 7256/23T, 7257/23T, 7258/23T, 7259/23T, 7260/23T	MEDOCHEMIE 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 manufacturi B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition

				of a new specificatio 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 /
PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	7243/23T, 7244/23T, 7245/23T, 7246/23T, 7247/23T, 7248/23T, 7249/23T, 7250/23T, 7251/23T	MEDOCHEMIE 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 manufacturi B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specificatio 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 /
LATAZ EYE DROPS, SOLUTION 50MCG/1ML(0.005% W/V)	LATAZ EYE DROPS, SOLUTION 50MCG/1ML(0.005% W/V)	8573/23T	RAFARM 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
ZITAMIN SOLUTION FOR INJECTION 5MG/ML	ZITAMIN SOLUTION FOR INJECTION 5MG/ML	1786/23T, 1787/23T	NORIDEM ENTERPRISES LTD	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that affects the product information B.II.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
ZITAMIN SOLUTION FOR	ZITAMIN SOLUTION FOR	1784/23T, 1785/23T	NORIDEM ENTERPRISES LTD	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished

INJECTION 7.5MG/ML	INJECTION 7.5MG/ML			product - Change in storage conditions of the finished product or the diluted/reconstituted product B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that affects the product information B.II.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
ZITAMIN SOLUTION FOR INJECTION 10MG/ML	ZITAMIN SOLUTION FOR INJECTION 10MG/ML	1782/23T, 1783/23T	NORIDEM ENTERPRISES LTD	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that affects the product information B.II.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
ZITAMIN SOLUTION FOR INJECTION 2MG/ML	ZITAMIN SOLUTION FOR INJECTION 2MG/ML	1788/23T, 1789/23T	NORIDEM ENTERPRISES LTD	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product B.II.e.6.a B.II.e.6.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that affects the product information B.II.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
PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG	PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG	7212/23T, 7213/23T	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 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
PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	7210/23T, 7211/23T	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 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
PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	7208/23T, 7209/23T	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 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
OFLOXIN TABLET, FILM COATED 200MG	OFLOXIN TABLET, FILM COATED 200MG	8533/23T, 8534/23T	CODAL-SYNTO LIMITED	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
RAPYDAN MEDICATED PLASTER	RAPYDAN MEDICATED PLASTER	8387/23T	EUROCEPT INTERNATIONAL B.V	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
TOBRADEX EYE OINTMENT	TOBRADEX EYE OINTMENT	7827/23T	NOVARTIS IRELAND LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient

LOVASYNT TABLET 20MG	LOVASYNT TABLET 20MG	8532/23T	CODAL SYNTO LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
QUETIAPINE/GENERICS TABLET, FILM COATED 25MG	QUETIAPINE/GENERICS TABLET, FILM COATED 25MG	3584/23T	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
QUETIAPINE/GENERICS TABLET, FILM COATED 100MG	QUETIAPINE/GENERICS TABLET, FILM COATED 100MG	3583/23T	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
QUETIAPINE/GENERICS TABLET, FILM COATED 200MG	QUETIAPINE/GENERICS TABLET, FILM COATED 200MG	3582/23T	MYLAN IRELAND LIMITED	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
METHOTREXATE TABLET, FILM COATED 2.5MG	METHOTREXATE TABLET, FILM COATED 2.5MG	8348/23T	REMEDICA LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/1000MG	SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/1000MG	3210/23T, 3211/23T, 3212/23T, 3213/23T, 3214/23T, 3215/23T, 3216/23T, 3217/23T, 3218/23T, 3219/23T	APC INSTYTUT SP. Z.O.O.	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished B.II.b.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 B.II.b.5.d B.II.b.5.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces
SITAGLIPTIN/METFORMIN APC MODIFIED-	SITAGLIPTIN/METFORMIN APC MODIFIED-	3220/23T, 3221/23T, 3222/23T, 3223/23T, 3224/23T, 3225/23T,	APC INSTYTUT SP. Z.O.O.	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality

RELEASE TABLET 50MG/500MG	RELEASE TABLET 50MG/500MG	3226/23T, 3227/23T, 3228/23T, 3229/23T		control testing of the finished 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 B.II.b.5.d B.II.b.5.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 100MG/1000MG	SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 100MG/1000MG	3200/23T, 3201/23T, 3202/23T, 3203/23T, 3204/23T, 3205/23T, 3206/23T, 3207/23T, 3208/23T, 3209/23T	APC INSTYTUT SP. Z.O.O.	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished B.II.b.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 B.II.b.5.d B.II.b.5.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces
CONVERIUM TABLET 300MG	CONVERIUM TABLET 300MG	7850/23T, 7851/23T, 7852/23T, 7853/23T	MEDOCHEMIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging

				site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc
CONVERIUM TABLET 150MG	CONVERIUM TABLET 150MG	7854/23T, 7855/23T, 7856/23T, 7857/23T	MEDOCHEMIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc
REMODULIN SOLUTION FOR INFUSION 1MG/ML	REMODULIN SOLUTION FOR INFUSION 1MG/ML	6335/23T	FERRER INTERNACIONAL S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
REMODULIN SOLUTION FOR INFUSION 2.5MG/ML	REMODULIN SOLUTION FOR INFUSION 2.5MG/ML	6334/23T	FERRER INTERNACIONAL S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
REMODULIN SOLUTION FOR	REMODULIN SOLUTION FOR	6333/23T	FERRER INTERNACIONAL S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL

INFUSION 10MG/ML	INFUSION 10MG/ML			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)
REMODULIN SOLUTION FOR INFUSION 5MG/ML	REMODULIN SOLUTION FOR INFUSION 5MG/ML	6336/23T	FERRER INTERNACIONAL S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
HEXARHINAL NASAL SPRAY, SOLUTION 1MG/ML	HEXARHINAL NASAL SPRAY, SOLUTION 1MG/ML	7390/23T, 7391/23T, 7392/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
OPTODROP-CO EYE DROPS, SOLUTION (2+0.5)%	OPTODROP-CO EYE DROPS, SOLUTION (2+0.5)%	8513/23T	RAFARM 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
VISPRING ADVANCE EYE DROPS, SOLUTION 0.5MG/ML	VISPRING ADVANCE EYE DROPS, SOLUTION 0.5MG/ML	7583/23T, 7584/23T, 7585/23T, 7586/23T, 7587/23T, 7588/23T, 7589/23T, 7590/23T, 7591/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EFAVIRENZ AUROBINDO TABLET, FILM COATED 600MG	EFAVIRENZ AUROBINDO TABLET, FILM COATED 600MG	7037/23T, 7038/23T, 7039/23T	AUROBINDO PHARMA (MALTA) LIMITED	B.I.a.1.z B.I.a.1.z - Addition of an alternative site for manufacture and/or storage of the AS (if it's not part of the same pharmaceutical group). If the site is already registered (and is in SIAMED) for QC-AS, there is no need to request a separate scope for a new type of testing of the AS. Indent also to be used in case of addit A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss
SEIZAL TABLET, DISPERSIBLE 200MG	SEIZAL TABLET, DISPERSIBLE 200MG	8342/23T	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
SEIZAL TABLET, DISPERSIBLE 5MG	SEIZAL TABLET, DISPERSIBLE 5MG	8346/23T	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
SEIZAL TABLET, DISPERSIBLE 25MG	SEIZAL TABLET, DISPERSIBLE 25MG	8345/23T	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
SEIZAL TABLET, DISPERSIBLE 50MG	SEIZAL TABLET, DISPERSIBLE 50MG	8344/23T	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
SEIZAL TABLET, DISPERSIBLE 100MG	SEIZAL TABLET, DISPERSIBLE 100MG	8343/23T	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
SEIZAL TABLET 25MG	SEIZAL TABLET 25MG	8380/23T	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
SEIZAL TABLET 100MG	SEIZAL TABLET 100MG	8378/23T	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
SEIZAL TABLET 50MG	SEIZAL TABLET 50MG	8379/23T	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
SEIZAL TABLET 200MG	SEIZAL TABLET 200MG	8377/23T	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
RAPYDAN MEDICATED PLASTER	RAPYDAN MEDICATED PLASTER	5525/23T, 5526/23T	EUROCEPT INTERNATIONAL B.V	B.III.1.a.z B.III.1.a.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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.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
LEMOXOL POWDER FOR SOLUTION FOR INJECTION 1G	LEMOXOL POWDER FOR SOLUTION FOR INJECTION 1G	6459/23T	NORIDEM ENTERPRISES LTD	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
EZETIMIBE /SIMVASTATIN ACCORD TABLET 10MG/20MG	EZETIMIBE /SIMVASTATIN ACCORD TABLET 10MG/20MG	6102/23T	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
EZETIMIBE /SIMVASTATIN ACCORD TABLET 10MG/10MG	EZETIMIBE /SIMVASTATIN ACCORD TABLET 10MG/10MG	6103/23T	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
DEMOLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 40MG/VIAL	DEMOLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 40MG/VIAL	6820/23T	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
PROPESS VAGINAL DELIVERY SYSTEM 10MG/UNIT	PROPESS VAGINAL DELIVERY SYSTEM 10MG/UNIT	null	FERRING HELLAS MEPE	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
SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	7896/23T, 7897/23T	ACCORD HEALTHCARE S.L.U	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.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
SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	7894/23T, 7895/23T	ACCORD HEALTHCARE S.L.U	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.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
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 20MG	PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 20MG	2631/23T, 2632/23T, 2633/23T	AUROBINDO PHARMA (MALTA) LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site A.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)*
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 40MG	PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 40MG	2628/23T, 2629/23T, 2630/23T	AUROBINDO PHARMA (MALTA) LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site A.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)*

RUPAFIN ORAL SOLUTION 1MG/ML	RUPAFIN ORAL SOLUTION 1MG/ML	7399/23T	J. URIACH Y COMPANIA S.A.	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
PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	6722/23T	BAXTER (HELLAS) EPE	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
SODIUM CHLORIDE + GLUCOSE/ BAXTER SOLUTION FOR INFUSION (0.9+5)% W/V	SODIUM CHLORIDE + GLUCOSE/ BAXTER SOLUTION FOR INFUSION (0.9+5)% W/V	6721/23T	BAXTER (HELLAS) EPE	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
ATANTO CAPSULE, HARD 80MG	ATANTO CAPSULE, HARD 80MG	1316/23T, 1317/23T, 1318/23T	PHARMATHEN S.A.	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size B.I.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 -
ATANTO CAPSULE, HARD 125MG AND 80MG	ATANTO CAPSULE, HARD 125MG AND 80MG	1310/23T, 1311/23T, 1312/23T	PHARMATHEN S.A.	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size

				B.I.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 -
ATANTO CAPSULE, HARD 125MG	ATANTO CAPSULE, HARD 125MG	1313/23T, 1314/23T, 1315/23T	PHARMATHEN S.A.	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -
LOSARTAN /HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	LOSARTAN /HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	7601/23T, 7602/23T	KRKA D.D. NOVO MESTO	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
GABAPENTIN ACCORD CAPSULE, HARD 400MG	GABAPENTIN ACCORD CAPSULE, HARD 400MG	8299/23T	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
GABAPENTIN ACCORD CAPSULE, HARD 300MG	GABAPENTIN ACCORD CAPSULE, HARD 300MG	8300/23T	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
ADRENALINE INJECTION 1MG/ML	ADRENALINE INJECTION 1MG/ML	8448/23T, 8449/23T	NORIDEM ENTERPRISES LTD	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
LIDOCAINE ACCORD SOLUTION FOR INJECTION 20MG/ML	LIDOCAINE ACCORD SOLUTION FOR INJECTION 20MG/ML	7809/23T	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
LIDOCAINE ACCORD SOLUTION FOR INJECTION 10MG/ML	LIDOCAINE ACCORD SOLUTION FOR INJECTION 10MG/ML	7810/23T	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
LEVOFLOXACIN VIOSER SOLUTION FOR INFUSION 5MG/ML	LEVOFLOXACIN VIOSER SOLUTION FOR INFUSION 5MG/ML	5443/23T	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	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
GLUCAGEN HYPOKIT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1MG	GLUCAGEN HYPOKIT POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1MG	7403/23T	NOVO NORDISK A/S	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
METHOTREXATE ACCORD SOLUTION FOR INJECTION 25MG/ML	METHOTREXATE ACCORD SOLUTION FOR INJECTION 25MG/ML	5420/23T	ACCORD HEALTHCARE S.L.U	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

BUDENOFALK UNO GASTRO-RESISTANT GRANULES 9MG	BUDENOFALK UNO GASTRO-RESISTANT GRANULES 9MG	7579/23T	DR. FALK PHARMA GMBH	B.II.b).1. a) Secondary packaging site variation Type IAIN (B.II.b.1.a): to add Logifarma S.r.l, Via Campobello 1, 00071 Pomezia, Italy as an alternative site responsible for secondary packaging of the finished product.
DELTIUS ORAL DROPS SOLUTION 10000IU/ML	DELTIUS ORAL DROPS SOLUTION 10000IU/ML	5819/22T, 5820/22T	ITF HELLAS A.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) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 CAPSULE, HARD 50000IU	DELTIUS CAPSULE, HARD 50000IU	5813/22T, 5814/22T	ITF HELLAS A.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) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 SOLUTION 50000IU/2.5 ML	DELTIUS ORAL SOLUTION 50000IU/2.5 ML	5811/22T, 5812/22T	ITF HELLAS A.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) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 SOLUTION 25000IU/2.5 ML	DELTIUS ORAL SOLUTION 25000IU/2.5 ML	5817/22T, 5818/22T	ITF HELLAS A.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) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 CAPSULE, HARD 25000IU	DELTIUS CAPSULE, HARD 25000IU	5815/22T, 5816/22T	ITF HELLAS A.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) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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	DELTIUS ORAL DROPS	3265/21T	ITF HELLAS A.E.	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in

SOLUTION 10000IU/ML	SOLUTION 10000IU/ML			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
DELTIUS ORAL DROPS SOLUTION 10000IU/ML	DELTIUS ORAL DROPS SOLUTION 10000IU/ML	9196/21T	ITF HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DELTIUS CAPSULE, HARD 50000IU	DELTIUS CAPSULE, HARD 50000IU	9195/21T	ITF HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DELTIUS ORAL SOLUTION 50000IU/2.5 ML	DELTIUS ORAL SOLUTION 50000IU/2.5 ML	9194/21T	ITF HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DELTIUS ORAL SOLUTION 25000IU/2.5 ML	DELTIUS ORAL SOLUTION 25000IU/2.5 ML	9197/21T	ITF HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DELTIUS CAPSULE, HARD 25000IU	DELTIUS CAPSULE, HARD 25000IU	9193/21T	ITF HELLAS A.E.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DELTIUS ORAL DROPS SOLUTION 10000IU/ML	DELTIUS ORAL DROPS SOLUTION 10000IU/ML	5836/23T	ITF HELLAS A.E.	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
DELTIUS CAPSULE, HARD 50000IU	DELTIUS CAPSULE, HARD 50000IU	5839/23T	ITF HELLAS A.E.	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
DELTIUS ORAL SOLUTION 50000IU/2.5 ML	DELTIUS ORAL SOLUTION 50000IU/2.5 ML	5838/23T	ITF HELLAS A.E.	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
DELTIUS ORAL SOLUTION 25000IU/2.5 ML	DELTIUS ORAL SOLUTION 25000IU/2.5 ML	5835/23T	ITF HELLAS A.E.	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
DELTIUS CAPSULE, HARD 25000IU	DELTIUS CAPSULE, HARD 25000IU	5837/23T	ITF HELLAS A.E.	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
CAPOLEV TABLET 32MG	CAPOLEV TABLET 32MG	8324/23T	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 TABLET 4MG	CAPOLEV TABLET 4MG	8327/23T	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 TABLET 16MG	CAPOLEV TABLET 16MG	8325/23T	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 TABLET 8MG	CAPOLEV TABLET 8MG	8326/23T	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
LEVOSYNT TABLET 100/10MG	LEVOSYNT TABLET 100/10MG	8349/23T	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
LEVOSYNT TABLET 250/25MG	LEVOSYNT TABLET 250/25MG	8350/23T	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
LEVOSYNT TABLET 250/25MG	LEVOSYNT TABLET 250/25MG	8252/23T	CODAL SYNTO LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LEVOSYNT TABLET 100/10MG	LEVOSYNT TABLET 100/10MG	8251/23T	CODAL SYNTO LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
COPAXON E SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG/ML	COPAXON E SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG/ML	6982/23T, 6983/23T, 6984/23T, 6985/23T	TEVA GMBH	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 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.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
COPAXON E SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG/ML	COPAXON E SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG/ML	6978/23T, 6979/23T, 6980/23T, 6981/23T	TEVA GMBH	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 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.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
CURILEN CAPSULE, HARD	CURILEN CAPSULE, HARD	7188/23T	UNI-PHARMA KLEON TSETIS	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented)

10MG/100MG	10MG/100MG		PHARMACEUTICAL LABORATORIES SA	name of the medicinal product - for Nationally Authorised Products
CURILEN CAPSULE, HARD 5MG/100MG	CURILEN CAPSULE, HARD 5MG/100MG	7189/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
MANTOMED TABLET, FILM COATED 20MG	MANTOMED TABLET, FILM COATED 20MG	3047/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM COATED 5MG	MANTOMED TABLET, FILM COATED 5MG	3046/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM COATED 10MG	MANTOMED TABLET, FILM COATED 10MG	3048/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM COATED 15MG	MANTOMED TABLET, FILM COATED 15MG	3045/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
METHOTREXATE TABLET, FILM COATED 2.5MG	METHOTREXATE TABLET, FILM COATED 2.5MG	8204/23T	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
ABIRATERONE/SANDOZ TABLET, FILM COATED 500MG	ABIRATERONE/SANDOZ TABLET, FILM COATED 500MG	6972/23T, 6973/23T, 6974/23T	SANDOZ PHARMACEUTICALS D.D.	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.z B.I.z - Quality change - Active substance - Other variation
AMLODIPIN ACCORD TABLET 10MG	AMLODIPIN ACCORD TABLET 10MG	8228/23T, 8229/23T	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an

				active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AMLODIPIN ACCORD TABLET 5MG	AMLODIPIN ACCORD TABLET 5MG	8230/23T, 8231/23T	ACCORD HEALTHCARE S.L.U	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AMLODIPIN ACCORD TABLET 10MG	AMLODIPIN ACCORD TABLET 10MG	7892/23T	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
AMLODIPIN ACCORD TABLET 5MG	AMLODIPIN ACCORD TABLET 5MG	7893/23T	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
APIXABAN FARMAPROJECTS TABLET, FILM COATED 2.5MG	APIXABAN FARMAPROJECTS TABLET, FILM COATED 2.5MG	4415/23T, 4416/23T	FARMAPROJECTS, S.A.U	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
APIXABAN FARMAPROJECTS TABLET, FILM COATED 5MG	APIXABAN FARMAPROJECTS TABLET, FILM COATED 5MG	4413/23T, 4414/23T	FARMAPROJECTS, S.A.U	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
GLIZOREM TABLET 80MG	GLIZOREM TABLET 80MG	8108/23T	REMEDICA 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
PACLITAXEL HOSPIRA CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXEL HOSPIRA CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	8074/23T, 8075/23T, 8076/23T	PFIZER HELLAS AE	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.z A.z - ADMINISTRATIVE CHANGES - Other variation
SOLPADEINE COLD & FLU CAPSULE, HARD 500MG/100MG/6.1MG	SOLPADEINE COLD & FLU CAPSULE, HARD 500MG/100MG/6.1MG	8688/22T	OMEGA PHARMA HELLAS S.A	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
TESTOGEL TRANSDERMAL GEL 16.2 MG/G	TESTOGEL TRANSDERMAL GEL 16.2 MG/G	7743/23T	LABORATOIRES BESINS INTERNATIONAL	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)
OCTAGAM SOLUTION FOR INFUSION 10%	OCTAGAM SOLUTION FOR INFUSION 10%	7595/23T	OCTAPHARMA (IP) SPRL	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
OCTAGAM SOLUTION FOR	OCTAGAM SOLUTION FOR	7596/23T	OCTAPHARMA (IP) SPRL	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in

INFUSION 50MG/ML	INFUSION 50MG/ML			the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	6346/23T	OCTAPHARMA (IP) SPRL	B.I.a.4.z B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other changes
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5 ML	FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5 ML	7564/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.g.5.c B.II.g.5.c - QUALITY CHANGES - FINISHED PRODUCT - Design Space and post approval change management protocol - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product
MONTELUKAST KRKA TABLET, CHEWABLE 4MG	MONTELUKAST KRKA TABLET, CHEWABLE 4MG	7056/23T	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
MONTELUKAST KRKA TABLET, FILM COATED 10MG	MONTELUKAST KRKA TABLET, FILM COATED 10MG	7057/23T	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
MONTELUKAST KRKA TABLET, CHEWABLE 5MG	MONTELUKAST KRKA TABLET, CHEWABLE 5MG	7055/23T	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
ATAZANAVIR REMEDICA CAPSULE, HARD 200MG	ATAZANAVIR REMEDICA CAPSULE, HARD 200MG	8062/23T	REMEDICA LTD	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATAZANAVIR REMEDICA	ATAZANAVIR REMEDICA	8061/23T	REMEDICA LTD	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH

CAPSULE, HARD 300MG	CAPSULE, HARD 300MG			
ATAZANAVIR REMEDICA CAPSULE, HARD 150MG	ATAZANAVIR REMEDICA CAPSULE, HARD 150MG	8063/23T	REMEDICA LTD	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATAZANAVIR REMEDICA CAPSULE, HARD 100MG	ATAZANAVIR REMEDICA CAPSULE, HARD 100MG	8064/23T	REMEDICA LTD	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TOBRADEX EYE DROPS, SUSPENSION 0,1% w/v + 0,3% w/v	TOBRADEX EYE DROPS, SUSPENSION 0,1% w/v + 0,3% w/v	6177/23T	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
ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 40MG	ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 40MG	7684/23T	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
ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 20MG	ESOMEPRAZOLE TAD CAPSULE, GASTRO-RESISTANT 20MG	7685/23T	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
FERINJECT DISPERSION FOR INJECTION /INFUSION 50MG IRON/ML	FERINJECT DISPERSION FOR INJECTION /INFUSION 50MG IRON/ML	2537/23T	VIFOR FRANCE	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*
SUGAMMADEX ANABIOSIS	SUGAMMADEX ANABIOSIS	7290/23T, 7291/23T, 7292/23T, 7293/23T, 7294/23T, 7295/23T	ANABIOSIS PC.	B.I.z B.I.z - Quality change - Active substance - Other variation B.I.a.2.e B.I.a.2.e - QUALITY

SOLUTION FOR INJECTION 100MG/ML	SOLUTION FOR INJECTION 100MG/ML			CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.I.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
REGAINE WOMEN'S FOAM CUTANEOUS FOAM 5% W/W	REGAINE WOMEN'S FOAM CUTANEOUS FOAM 5% W/W	7597/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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
SYNTOCLAV TABLET, FILM COATED 875/125MG	SYNTOCLAV TABLET, FILM COATED 875/125MG	8172/23T	CODAL-SYNTO LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
METHOTREXATE ACCORD SOLUTION FOR INJECTION 25MG/ML	METHOTREXATE ACCORD SOLUTION FOR INJECTION 25MG/ML	2054/23T	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
STERCORE TABLET, FILM COATED 1MG	STERCORE TABLET, FILM COATED 1MG	4968/23T	MEDOCHEMIE LTD	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms
STERCORE TABLET, FILM COATED 2MG	STERCORE TABLET, FILM COATED 2MG	4967/23T	MEDOCHEMIE LTD	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms
LANSO GASTRO-RESISTAN	LANSO GASTRO-RESISTAN	8054/23T	IASIS PHARMACEU	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the

T CAPSULE, HARD 30MG	T CAPSULE, HARD 30MG		TICALS HELLAS SA	manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
MELOX SOLUTION FOR INJECTION 10MG/ML	MELOX SOLUTION FOR INJECTION 10MG/ML	5874/23T	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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 80MG(8000 IU)/0.8ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 80MG(8000 IU)/0.8ML	7310/23T, 7311/23T	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 - Change in the holding time of an intermediate B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG(4000 IU)/0.4ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG(4000 IU)/0.4ML	7314/23T, 7315/23T	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 - Change in the holding time of an intermediate B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 60MG(6000 IU)/0.6ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 60MG(6000 IU)/0.6ML	7312/23T, 7313/23T	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 - Change in the holding time of an intermediate B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas
CLEXANE SOLUTION FOR INJECTION IN PREFILLED	CLEXANE SOLUTION FOR INJECTION IN PREFILLED	7316/23T, 7317/23T	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

SYRINGE 20MG(2000 IU)/0.2ML	SYRINGE 20MG(2000 IU)/0.2ML			product - Change in the holding time of an intermediate B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 80MG(8000 IU)/0.8ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 80MG(8000 IU)/0.8ML	6233/23T	SANOFI WINTHROP INDUSTRIE.	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG(4000 IU)/0.4ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG(4000 IU)/0.4ML	6235/23T	SANOFI WINTHROP INDUSTRIE.	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG(2000 IU)/0.2ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG(2000 IU)/0.2ML	6236/23T	SANOFI WINTHROP INDUSTRIE.	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 60MG(6000 IU)/0.6ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 60MG(6000 IU)/0.6ML	6234/23T	SANOFI WINTHROP INDUSTRIE.	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG(2000 IU)/0.2ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG(2000 IU)/0.2ML	4927/23T, 4928/23T	SANOFI WINTHROP INDUSTRIE.	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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 80MG(8000 IU)/0.8ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 80MG(8000 IU)/0.8ML	4921/23T, 4922/23T	SANOFI WINTHROP INDUSTRIE.	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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG(4000 IU)/0.4ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG(4000 IU)/0.4ML	4925/23T, 4926/23T	SANOFI WINTHROP INDUSTRIE.	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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 60MG(6000 IU)/0.6ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 60MG(6000 IU)/0.6ML	4923/23T, 4924/23T	SANOFI WINTHROP INDUSTRIE.	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
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 80MG(8000 IU)/0.8ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 80MG(8000 IU)/0.8ML	4556/23T, 4557/23T	SANOFI WINTHROP INDUSTRIE.	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG(4000 IU)/0.4ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG(4000 IU)/0.4ML	4560/23T, 4561/23T	SANOFI WINTHROP INDUSTRIE.	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
CLEXANE SOLUTION FOR	CLEXANE SOLUTION FOR	4558/23T, 4559/23T	SANOFI WINTHROP INDUSTRIE.	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval

INJECTION IN PREFILLED SYRINGE 60MG(6000 IU)/0.6ML	INJECTION IN PREFILLED SYRINGE 60MG(6000 IU)/0.6ML			change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG(2000 IU)/0.2ML	CLEXANE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG(2000 IU)/0.2ML	4562/23T, 4563/23T	SANOFI WINTHROP INDUSTRIE.	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval change management protocols - Implementation of changes foreseen in an approved change management protocol - Implementation of a change for a biological/immunological medicinal product B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	VISIOLATAN EYE DROPS, SOLUTION 50MCG/ML	6210/23T	BAUSCH + LOMB 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
ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	6546/23T	ALTAN PHARMACEUTICALS S.A.	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits
ESMERON SOLUTION FOR INJECTION 50MG/5ML	ESMERON SOLUTION FOR INJECTION 50MG/5ML	8016/23T	MSD AFVEE	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
MABRON RETARD TABLET, PROLONGED-RELEASE 100MG	MABRON RETARD TABLET, PROLONGED-RELEASE 100MG	7813/23T	MEDOCHEMIE LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MABRON RETARD TABLET, PROLONGED-RELEASE 200MG	MABRON RETARD TABLET, PROLONGED-RELEASE 200MG	7811/23T	MEDOCHEMIE LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MABRON RETARD TABLET, PROLONGED-	MABRON RETARD TABLET, PROLONGED-	7812/23T	MEDOCHEMIE LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

RELEASE 150MG	RELEASE 150MG			
MAINTELY TE SOLUTION FOR INFUSION 50MG/ML	MAINTELY TE SOLUTION FOR INFUSION 50MG/ML	7491/23T, 7492/23T, 7493/23T	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
SEVOFLURANE-PIRAMAL INHALATION VAPOUR, LIQUID 100% V/V	SEVOFLURANE-PIRAMAL INHALATION VAPOUR, LIQUID 100% V/V	6362/23T	PIRAMAL CRITICAL CARE B.V.	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
MEDOCEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G/VIAL	MEDOCEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G/VIAL	7819/23T, 7820/23T, 7821/23T	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
MEDOCEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	MEDOCEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	7822/23T, 7823/23T, 7824/23T	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
SPECENIB TABLET, FILM COATED 50MG	SPECENIB TABLET, FILM COATED 50MG	7835/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size
SPECENIB TABLET, FILM COATED 100MG	SPECENIB TABLET, FILM COATED 100MG	7832/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size
SPECENIB TABLET, FILM	SPECENIB TABLET, FILM	7831/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active

COATED 140MG	COATED 140MG			substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size
SPECENIB TABLET, FILM COATED 20MG	SPECENIB TABLET, FILM COATED 20MG	7836/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size
SPECENIB TABLET, FILM COATED 80MG	SPECENIB TABLET, FILM COATED 80MG	7833/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size
SPECENIB TABLET, FILM COATED 70MG	SPECENIB TABLET, FILM COATED 70MG	7834/23T	REMEDICA LTD	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size
CEFTRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1G/VIAL	CEFTRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1G/VIAL	8001/23T	CODAL-SYNTO LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CEFTRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500MG/VIAL	CEFTRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500MG/VIAL	8002/23T	CODAL-SYNTO LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FELDENE TABLET, DISPERSIBLE 20MG	FELDENE TABLET, DISPERSIBLE 20MG	6428/23T, 6429/23T, 6430/23T, 6431/23T, 6432/23T, 6433/23T, 6434/23T, 6435/23T, 6436/23T	PFIZER HELLAS AE	B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.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
FELDENE TABLET, DISPERSIBLE 20MG	FELDENE TABLET, DISPERSIBLE 20MG	6417/23T	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
INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGE 18.000 ANTI-XA IU/0.9ML	INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGE 18.000 ANTI-XA IU/0.9ML	4566/23T	LEO PHARMA A/S	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
INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGE 4.500 ANTI-XA IU/0.45ML	INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGE 4.500 ANTI-XA IU/0.45ML	4569/23T	LEO PHARMA A/S	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
INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGE 14.000 ANTI-XA IU/0.7ML	INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGE 14.000 ANTI-XA IU/0.7ML	4567/23T	LEO PHARMA A/S	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
INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGE 10.000 ANTI-XA IU/0.5ML	INNOHEP SOLUTION FOR INJECTION IN PREFILLED SYRINGE 10.000 ANTI-XA IU/0.5ML	4568/23T	LEO PHARMA A/S	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
ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 40MG	ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 40MG	7688/23T	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
ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 20MG	ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 20MG	7689/23T	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

ALMIRAL GEL 1% W/W	ALMIRAL GEL 1% W/W	8280/23T, 8281/23T, 8282/23T	MEDOCHEMIE LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
TOPOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	TOPOTECAN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	7722/23T	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
FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1G	7572/23T	OCTAPHARMA (IP) SPRL	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process of a sterile finished product after the primary packaging step
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 180MG	MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 180MG	7340/23T	ACCORD HEALTHCARE S.L.U	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 360MG	MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 360MG	7339/23T	ACCORD HEALTHCARE S.L.U	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
FLUDARABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTION 25MG/ML	FLUDARABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTION 25MG/ML	7617/23T	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
FINASTERID AUROBINDO TABLET, FILM COATED 5MG	FINASTERID AUROBINDO TABLET, FILM COATED 5MG	2533/23T, 2534/23T	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
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 180MG	MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 180MG	7225/23T	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
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 360MG	MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 360MG	7224/23T	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
GAVISCON DOUBLE ACTION TABLET, CHEWABLE	GAVISCON DOUBLE ACTION TABLET, CHEWABLE	5620/23T, 5621/23T, 5622/23T, 5623/23T, 5624/23T	RECKITT BENCKISER HELLAS HEALTHCARE SA	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finishe B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w B.II.b.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

SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	7877/23T	ACCORD HEALTHCARE S.L.U	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
SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	7878/23T	ACCORD HEALTHCARE S.L.U	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
NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	7425/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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)
NICORETTE QUICKSPRAY OROMUCOSAL SPRAY, SOLUTION 1MG/DOSE	NICORETTE QUICKSPRAY OROMUCOSAL SPRAY, SOLUTION 1MG/DOSE	7426/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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)
LEVOXACIN TABLET, FILM COATED 250MG	LEVOXACIN TABLET, FILM COATED 250MG	9778/20T	SAPIENS PHARMACEUTICALS LTD	C.I.11 b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
LEVOXACIN TABLET, FILM COATED 500MG	LEVOXACIN TABLET, FILM COATED 500MG	9777/20T	SAPIENS PHARMACEUTICALS LTD	C.I.11 b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
VERMOX TABLET 100MG	VERMOX TABLET 100MG	7494/23T	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
VERMOX ORAL SUSPENSION 2%	VERMOX ORAL SUSPENSION 2%	7495/23T	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
LEVOXACIN SOLUTION FOR INFUSION 5MG/ML	LEVOXACIN SOLUTION FOR INFUSION 5MG/ML	9779/20T	SAPIENS PHARMACEUTICALS LTD	C.I.11 b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
ZYVOXID SOLUTION FOR INFUSION 2MG/ML	ZYVOXID SOLUTION FOR INFUSION 2MG/ML	4310/23T, 4311/23T	PFIZER HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* 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)
ZYVOXID TABLET, FILM COATED 600MG	ZYVOXID TABLET, FILM COATED 600MG	4308/23T, 4309/23T	PFIZER HELLAS AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* 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)
PALONAN SOLUTION FOR INJECTION 250MCG/5ML	PALONAN SOLUTION FOR INJECTION 250MCG/5ML	5812/21T	ANFARM HELLAS S.A.	B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)
PALONAN SOLUTION FOR	PALONAN SOLUTION FOR	1762/21T	ANFARM HELLAS S.A.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF

INJECTION 250MCG/5 ML	INJECTION 250MCG/5 ML			
BUFAR EASYHALE R POWDER FOR INHALATIO N 320/9MCG/I NHALATIO N	BUFAR EASYHALE R POWDER FOR INHALATIO N 320/9MCG/I NHALATIO N	5421/22T	ORION CORPORATIO N (ORION PHARMA)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 EASYHALE R POWDER FOR INHALATIO N 160/4.5MC G/INHALAT ION	BUFAR EASYHALE R POWDER FOR INHALATIO N 160/4.5MC G/INHALAT ION	5422/22T	ORION CORPORATIO N (ORION PHARMA)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 EASYHALE R POWDER FOR INHALATIO N 80MCG/4.5 MCG/INHA LATION	BUFAR EASYHALE R POWDER FOR INHALATIO N 80MCG/4.5 MCG/INHA LATION	5423/22T	ORION CORPORATIO N (ORION PHARMA)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SAGILIA TABLET 1MG	SAGILIA TABLET 1MG	1122/23T	MEDOCHEMIE LTD	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
ROSUVAD OR TABLET, FILM COATED 40MG	ROSUVAD OR TABLET, FILM COATED 40MG	3398/23T	TAD PHARMA GMBH	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
ROSUVAD OR TABLET, FILM	ROSUVAD OR TABLET, FILM	3401/23T	TAD PHARMA GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product

COATED 5MG	COATED 5MG			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
ROSUVAD OR TABLET, FILM COATED 20MG	ROSUVAD OR TABLET, FILM COATED 20MG	3399/23T	TAD PHARMA GMBH	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
ROSUVAD OR TABLET, FILM COATED 10MG	ROSUVAD OR TABLET, FILM COATED 10MG	3400/23T	TAD PHARMA GMBH	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
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 200IU/ML(1000IU/5ML)	OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 200IU/ML(1000IU/5ML)	6913/23T	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
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 100IU/ML(500IU/5ML)	OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 100IU/ML(500IU/5ML)	6914/23T	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
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250/500 (50 IU/ml)	OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250/500 (50 IU/ml)	6916/23T	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
OCTANATE POWDER AND SOLVENT	OCTANATE POWDER AND SOLVENT	6915/23T	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 -

FOR SOLUTION FOR INJECTION 1000 (100 IU/ml)	FOR SOLUTION FOR INJECTION 1000 (100 IU/ml)			Minor changes to an approved test procedure
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 200IU/ML(1000IU/5ML)	OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 200IU/ML(1000IU/5ML)	6048/23T	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 100IU/ML(500IU/5ML)	OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 100IU/ML(500IU/5ML)	6049/23T	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250/500 (50 IU/ml)	OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 250/500 (50 IU/ml)	6051/23T	OCTAPHARMA (IP) SPRL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000 (100 IU/ml)	OCTANATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000 (100 IU/ml)	6050/23T	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
VENLAXIN TABLET, PROLONGED-RELEASE 75MG	VENLAXIN TABLET, PROLONGED-RELEASE 75MG	8068/23T	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
VENLAXIN TABLET, PROLONGED-RELEASE 225MG	VENLAXIN TABLET, PROLONGED-RELEASE 225MG	8066/23T	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
VENLAXIN TABLET, PROLONGED-RELEASE 150MG	VENLAXIN TABLET, PROLONGED-RELEASE 150MG	8067/23T	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
TENORETIC TABLET, FILM COATED 100MG/25MG	TENORETIC TABLET, FILM COATED 100MG/25MG	2986/23T, 2987/23T, 2988/23T, 2989/23T, 2990/23T, 2991/23T, 2992/23T, 2993/23T, 2994/23T	ATNAHS PHARMA NETHERLANDS B.V.	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufac B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufac B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufac B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch releas B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release ar B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certif
LAMOTRIX TABLET 200MG	LAMOTRIX TABLET 200MG	8018/23T	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
LAMOTRIX TABLET 100MG	LAMOTRIX TABLET 100MG	8019/23T	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
LAMOTRIX TABLET 25MG	LAMOTRIX TABLET 25MG	8021/23T	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
LAMOTRIX TABLET 50MG	LAMOTRIX TABLET 50MG	8020/23T	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
MEDOFLOXINE TABLET, FILM COATED 200MG	MEDOFLOXINE TABLET, FILM COATED 200MG	8014/23T, 8015/23T	MEDOCHEMIE LTD	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
FLIXOTIDE DISKUS POWDER FOR INHALATION 250MCG	FLIXOTIDE DISKUS POWDER FOR INHALATION 250MCG	7288/23T	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
FLIXOTIDE DISKUS POWDER FOR INHALATION 100MCG	FLIXOTIDE DISKUS POWDER FOR INHALATION 100MCG	7289/23T	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
DUINUM TABLET 50MG	DUINUM TABLET 50MG	8029/23T	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)*
UTROGESTAN VAGINAL CAPSULE, SOFT 300MG	UTROGESTAN VAGINAL CAPSULE, SOFT 300MG	7378/23T	BESINS HEALTHCARE IRELAND LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
UTROGESTAN VAGINAL CAPSULE, SOFT 300MG	UTROGESTAN VAGINAL CAPSULE, SOFT 300MG	6087/23T	BESINS HEALTHCARE IRELAND LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	7828/23T	MEDOCHEMIE LTD	B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	7829/23T	MEDOCHEMIE LTD	B.II.b.1.f B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML	PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML	4199/23T	FRESENIUS KABI HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment

PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML IN PRE-FILLED SYRINGE	PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML IN PRE-FILLED SYRINGE	4196/23T	FRESENIUS KABI HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML	PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML	4198/23T	FRESENIUS KABI HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML IN PRE-FILLED SYRINGE	PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML IN PRE-FILLED SYRINGE	4197/23T	FRESENIUS KABI HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML	PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML	6111/21T	FRESENIUS KABI HELLAS AE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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)
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION	PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION	6110/21T	FRESENIUS KABI HELLAS AE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar

/ INFUSION 20MG/ML	/ INFUSION 20MG/ML			medicinal products following assessment of the 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)
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML IN PRE-FILLED SYRINGE	PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML IN PRE-FILLED SYRINGE	6108/21T	FRESENIUS KABI HELLAS AE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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)
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML IN PRE-FILLED SYRINGE	PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML IN PRE-FILLED SYRINGE	6109/21T	FRESENIUS KABI HELLAS AE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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)
ENTEVIRE M TABLET, FILM COATED 1MG	ENTEVIRE M TABLET, FILM COATED 1MG	7939/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ENTEVIRE M TABLET, FILM COATED 0.5MG	ENTEVIRE M TABLET, FILM COATED 0.5MG	7940/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
PIPERACIL LIN + TAZOBACT AM/GENER ICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (4G/0.5G)/V IAL	PIPERACIL LIN + TAZOBACT AM/GENER ICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (4G/0.5G)/V IAL	7369/23T	MYLAN IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PIPERACIL LIN + TAZOBACT AM/GENER ICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (2G/0.25G)/ VIAL	PIPERACIL LIN + TAZOBACT AM/GENER ICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (2G/0.25G)/ VIAL	7370/23T	MYLAN IRELAND LIMITED	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
CARBOPLA TIN/HOSPI RA SOLUTION FOR INFUSION 10MG/ML	CARBOPLA TIN/HOSPI RA SOLUTION FOR INFUSION 10MG/ML	7994/23T	PFIZER HELLAS AE	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
ONCOTICE POWDER FOR SOLUTION FOR INFUSION	ONCOTICE POWDER FOR SOLUTION FOR INFUSION	7992/23T	MSD AFVEE	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
NOPRILAM DT POWDER FOR ORAL SUSPENSI ON (400MG/57 MG)/5ML	NOPRILAM DT POWDER FOR ORAL SUSPENSI ON (400MG/57 MG)/5ML	8017/23T	BIAL-PORTELA & CA, SA	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate
MUCOSOL VAN SYRUP 30MG/5ML	MUCOSOL VAN SYRUP 30MG/5ML	993/23T, 994/23T, 995/23T, 996/23T, 997/23T, 998/23T, 999/23T, 1000/23T	OPELLA HEALTHCARE GREECE SINGLE	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of

			MEMBER LTD (OPELLA E.P.E.)	B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipien 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.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site fo
ALLOPURINOL ACCORD TABLET 100MG	ALLOPURINOL ACCORD TABLET 100MG	7366/23T, 7367/23T	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 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
TOBI SOLUTION FOR INHALATION 300MG/5ML	TOBI SOLUTION FOR INHALATION 300MG/5ML	6791/23T, 6792/23T, 6793/23T	VIATRIS HEALTHCARE LIMITED.	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or 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
PLENDIL TABLET, PROLONGED-RELEASE 5MG	PLENDIL TABLET, PROLONGED-RELEASE 5MG	7205/23T	ASTRAZENECA AB	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
PLENDIL TABLET,	PLENDIL TABLET,	7205/23T	ASTRAZENECA AB	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

PROLONGED-RELEASE 5MG	PROLONGED-RELEASE 5MG			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
PLENDIL TABLET, PROLONGED-RELEASE 10MG	PLENDIL TABLET, PROLONGED-RELEASE 10MG	7204/23T	ASTRAZENECA AB	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
PLENDIL TABLET, PROLONGED-RELEASE 10MG	PLENDIL TABLET, PROLONGED-RELEASE 10MG	7204/23T	ASTRAZENECA AB	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
PLENDIL TABLET, PROLONGED-RELEASE 2.5MG	PLENDIL TABLET, PROLONGED-RELEASE 2.5MG	7206/23T	ASTRAZENECA AB	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
PLENDIL TABLET, PROLONGED-RELEASE 2.5MG	PLENDIL TABLET, PROLONGED-RELEASE 2.5MG	7206/23T	ASTRAZENECA AB	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
PLENDIL TABLET, PROLONGED-RELEASE 5MG	PLENDIL TABLET, PROLONGED-RELEASE 5MG	4918/23T	ASTRAZENECA AB	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

PLENDIL TABLET, PROLONGED-RELEASE 10MG	PLENDIL TABLET, PROLONGED-RELEASE 10MG	4920/23T	ASTRAZENECA AB	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
PLENDIL TABLET, PROLONGED-RELEASE 2.5MG	PLENDIL TABLET, PROLONGED-RELEASE 2.5MG	4919/23T	ASTRAZENECA AB	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
COROTROPE TABLET 5MG	COROTROPE TABLET 5MG	7912/23T, 7913/23T, 7914/23T, 7915/23T	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 - Eur B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.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
PROPESS VAGINAL DELIVERY SYSTEM 10MG/UNIT	PROPESS VAGINAL DELIVERY SYSTEM 10MG/UNIT	3571/23T	FERRING HELLAS MEPE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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	ZITAMIN SOLUTION FOR INJECTION 2MG/ML	5269/23T	NORIDEM ENTERPRISES 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)*
ZITAMIN SOLUTION FOR INJECTION 7.5MG/ML	ZITAMIN SOLUTION FOR INJECTION 7.5MG/ML	5267/23T	NORIDEM ENTERPRISES 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)*
ZITAMIN SOLUTION FOR INFUSION 2MG/ML	ZITAMIN SOLUTION FOR INFUSION 2MG/ML	5270/23T	NORIDEM ENTERPRISES 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)*
ZITAMIN SOLUTION FOR INJECTION 10MG/ML	ZITAMIN SOLUTION FOR INJECTION 10MG/ML	5266/23T	NORIDEM ENTERPRISES 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)*
ZITAMIN SOLUTION FOR INJECTION 5MG/ML	ZITAMIN SOLUTION FOR INJECTION 5MG/ML	5268/23T	NORIDEM ENTERPRISES 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)*
SUGAMMADEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	SUGAMMADEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	8201/23T	SAPIENS 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)
DARUNAVIR ACCORD TABLET, FILM COATED 600MG	DARUNAVIR ACCORD TABLET, FILM COATED 600MG	4601/22T	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
DARUNAVIR ACCORD TABLET, FILM COATED 800MG	DARUNAVIR ACCORD TABLET, FILM COATED 800MG	4600/22T	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
LOCERYL MEDICATED NAIL LACQUER 5% (W/V)	LOCERYL MEDICATED NAIL LACQUER 5% (W/V)	8271/22T, 8272/22T, 4287/23T	GALDERMA INTERNATIONAL,FRANCE	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. dele B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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.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
SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	7537/23T, 7538/23T	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 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
SITAGLIPTIN/MYLAN TABLET, FILM COATED 25MG	SITAGLIPTIN/MYLAN TABLET, FILM COATED 25MG	8904/22T	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SITAGLIPTIN/MYLAN TABLET, FILM COATED 100MG	SITAGLIPTIN/MYLAN TABLET, FILM COATED 100MG	8902/22T	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	SITAGLIPTIN/MYLAN TABLET, FILM COATED 50MG	8903/22T	MYLAN IRELAND LIMITED	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
HYDROCORTISONE ACTIVASE	HYDROCORTISONE ACTIVASE	8306/21T	ACTIVASE PHARMACEUTICALS LTD	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

TABLET 10MG	TABLET 10MG			MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling 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 ACTIVASE TABLET 20MG	HYDROCORTISONE ACTIVASE TABLET 20MG	8307/21T	ACTIVASE PHARMACEUTICALS LTD	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 ACTIVASE TABLET 10MG	HYDROCORTISONE ACTIVASE TABLET 10MG	5558/22T	ACTIVASE 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)
HYDROCORTISONE ACTIVASE TABLET 20MG	HYDROCORTISONE ACTIVASE TABLET 20MG	5557/22T	ACTIVASE 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)
SEROQUEL XR TABLET, PROLONGED-RELEASE 300MG	SEROQUEL XR TABLET, PROLONGED-RELEASE 300MG	3703/23T	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	SEROQUEL XR TABLET, PROLONGED-RELEASE 400MG	3704/23T	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	PLENDIL TABLET, PROLONGED-RELEASE 5MG	3891/23T	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	SEROQUEL TABLET, FILM COATED 100MG	3699/23T	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	SEROQUEL TABLET, FILM COATED 200MG	3700/23T	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	SEROQUEL TABLET, FILM COATED 25MG	3698/23T	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	SEROQUEL XR TABLET, PROLONGED-RELEASE 200MG	3702/23T	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	SEROQUEL XR TABLET, PROLONGED-RELEASE 50MG	3701/23T	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	SEROQUEL XR TABLET, PROLONGED-RELEASE 150MG	3705/23T	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	SYMBICORT TURBUHALER POWDER FOR INHALATION 160MCG/4.5MCG	3707/23T	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	SYMBICORT PRESSURISED INHALATION, SUSPENSION 160/4.5MCG/ACTUATION	3710/23T	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	SYMBICORT TURBUHALER POWDER FOR INHALATION 80MCG/4.5MCG	3706/23T	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 320MCG/9MCG	SYMBICORT TURBUHALER POWDER FOR INHALATION 320MCG/9MCG	3709/23T	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SYMBICORT PRESSURI	SYMBICORT PRESSURI	3708/23T	ASTRAZENECA AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name

SED INHALATIO N, SUSPENSI ON 80MCG/2.2 5MCG/ACT UATION	SED INHALATIO N, SUSPENSI ON 80MCG/2.2 5MCG/ACT UATION			and/or address of the marketing authorisation holder
PLENDIL TABLET, PROLONG ED-RELEASE 10MG	PLENDIL TABLET, PROLONG ED-RELEASE 10MG	3892/23T	ASTRAZENEC A AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PLENDIL TABLET, PROLONG ED-RELEASE 2.5MG	PLENDIL TABLET, PROLONG ED-RELEASE 2.5MG	3890/23T	ASTRAZENEC A AB	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DARUNAVI R ACCORD TABLET, FILM COATED 600MG	DARUNAVI R ACCORD TABLET, FILM COATED 600MG	1630/23T	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
DARUNAVI R ACCORD TABLET, FILM COATED 800MG	DARUNAVI R ACCORD TABLET, FILM COATED 800MG	1629/23T	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
ROCURONI UM B.BRAUN SOLUTION FOR INJECTION OR INFUSION 10MG/ML	ROCURONI UM B.BRAUN SOLUTION FOR INJECTION OR INFUSION 10MG/ML	2802/23T, 2803/23T, 2804/23T	B. BRAUN MELSUNGEN AG	B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits
LIPOCOMB CAPSULE, HARD 10MG/10M G	LIPOCOMB CAPSULE, HARD 10MG/10M G	2387/23T	EGIS PHARMACEU TICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	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
LIPOCOMB CAPSULE, HARD 20MG/10MG	LIPOCOMB CAPSULE, HARD 20MG/10MG	2386/23T	EGIS PHARMACEUTICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	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
LONATA EYE DROPS, SOLUTION (50MCG/5MG)/ML	LONATA EYE DROPS, SOLUTION (50MCG/5MG)/ML	4991/23T	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
EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	4312/23T	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
DIENOGEST BESINS TABLET 2MG	DIENOGEST BESINS TABLET 2MG	6002/23T	LABORATOIRES BESINS INTERNATIONAL	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
HYDROCORTISONE RENATA TABLET 20MG	HYDROCORTISONE RENATA TABLET 20MG	6896/23T, 6897/23T	RENATA PHARMACEUTICALS (IRELAND) LIMITED	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
HYDROCORTISONE RENATA TABLET 10MG	HYDROCORTISONE RENATA TABLET 10MG	6898/23T, 6899/23T	RENATA PHARMACEUTICALS (IRELAND) LIMITED	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or

				quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA TABLET, FILM COATED 200MG/245MG	4565/23T	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)
APIXABAN/MYLAN TABLET, FILM COATED 2.5MG	APIXABAN/MYLAN TABLET, FILM COATED 2.5MG	5090/23T	MYLAN 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
APIXABAN/MYLAN TABLET, FILM COATED 5MG	APIXABAN/MYLAN TABLET, FILM COATED 5MG	5091/23T	MYLAN 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
ANDROXIL CUTANEOUS SOLUTION 5%	ANDROXIL CUTANEOUS SOLUTION 5%	2577/22T, 2578/22T, 2579/22T, 2580/22T, 2581/22T	LABORATOIRES BAILLEUL S.A	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.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

ANDROXIL CUTANEOUS SOLUTION 2%	ANDROXIL CUTANEOUS SOLUTION 2%	2582/22T, 2583/22T, 2584/22T, 2585/22T, 2586/22T	LABORATOIRES BAILLEUL S.A	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.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
ANGUSTA TABLET 25MCG	ANGUSTA TABLET 25MCG	5920/23T	AZANTA DANMARK A/S.	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
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	5432/23T	BIOTEST PHARMA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ALLOPURINOL ACCORD TABLET 100MG	ALLOPURINOL ACCORD TABLET 100MG	6088/23T	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
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L	5652/23T	BIOTEST PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
DEXMEDETOMIDINE/ KABI CONCENT	DEXMEDETOMIDINE/ KABI CONCENT	5664/23T	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

RATE FOR SOLUTION FOR INFUSION 100MCG/ML	RATE FOR SOLUTION FOR INFUSION 100MCG/ML			product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
ZATEVEN TABLET 10MG/80MG	ZATEVEN TABLET 10MG/80MG	5049/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
ZATEVEN TABLET 10MG/20MG	ZATEVEN TABLET 10MG/20MG	5051/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
ZATEVEN TABLET 10MG/10MG	ZATEVEN TABLET 10MG/10MG	5052/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
ZATEVEN TABLET 10MG/40MG	ZATEVEN TABLET 10MG/40MG	5050/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
INFLUVAC SUB-UNIT TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	INFLUVAC SUB-UNIT TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	5398/23T	VIATRIS HEALTHCARE LIMITED.	B.I.a.5.a B.I.a.5.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes to the active substance of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza
FLUDEOXYGLUCOSE (18F) GE HEALTHCARE SOLUTION FOR INJECTION 250MBQ/ML	FLUDEOXYGLUCOSE (18F) GE HEALTHCARE SOLUTION FOR INJECTION 250MBQ/ML	3112/23T, 3113/23T, 3114/23T, 3115/23T, 3116/23T, 3117/23T, 3118/23T, 3119/23T	GE HEALTHCARE 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 app B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finis B.I.a.1.z B.I.a.1.z - Addition of an alternative site for manufacture and/or storage of the AS (if it's not part of the same pharmaceutical group). If the site is alr 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 produc 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 proces
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG/ML	COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 20MG/ML	6214/23T, 6215/23T	TEVA 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
COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG/ML	COPAXONE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG/ML	6212/23T, 6213/23T	TEVA 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
PLENDIL TABLET, PROLONGED-RELEASE 5MG	PLENDIL TABLET, PROLONGED-RELEASE 5MG	5717/23T	ASTRAZENECA AB	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PLENDIL TABLET, PROLONGED-RELEASE 10MG	PLENDIL TABLET, PROLONGED-RELEASE 10MG	5716/23T	ASTRAZENECA AB	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
PLENDIL TABLET, PROLONGED-RELEASE 2.5MG	PLENDIL TABLET, PROLONGED-RELEASE 2.5MG	5718/23T	ASTRAZENECA AB	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
MEDOLIN TABLET 4MG	MEDOLIN TABLET 4MG	7139/23T	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
MEDOLIN TABLET 2MG	MEDOLIN TABLET 2MG	7140/23T	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
GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	GADOVIST SOLUTION FOR INJECTION 1MMOL/ML	6315/23T	BAYER HELLAS ABEE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FELDENE TABLET, DISPERSIBLE 20MG	FELDENE TABLET, DISPERSIBLE 20MG	8534/22T	PFIZER HELLAS AE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
PONSTAN FORTE TABLET, FILM COATED 500MG	PONSTAN FORTE TABLET, FILM COATED 500MG	8535/22T	PFIZER HELLAS AE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation
VALGANCICLOVIR ACCORD TABLET, FILM COATED 450MG	VALGANCICLOVIR ACCORD TABLET, FILM COATED 450MG	5425/23T	ACCORD HEALTHCARE S.L.U	B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File
AMLODIPIN ACCORD TABLET 5MG	AMLODIPIN ACCORD TABLET 5MG	7343/23T, 7344/23T	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 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
AMLODIPIN ACCORD TABLET 10MG	AMLODIPIN ACCORD TABLET 10MG	7341/23T, 7342/23T	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 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

ALGOFEN TABLET 500MG	ALGOFEN TABLET 500MG	7826/23T	MEDOCHEMIE 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
CIPROFLOXACIN KABI SOLUTION FOR INFUSION 2MG/ML(400MG/200ML)	CIPROFLOXACIN KABI SOLUTION FOR INFUSION 2MG/ML(400MG/200ML)	6457/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
CIPROFLOXACIN KABI SOLUTION FOR INFUSION 2MG/ML(200MG/100ML)	CIPROFLOXACIN KABI SOLUTION FOR INFUSION 2MG/ML(200MG/100ML)	6458/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
MONTELUKAST ACCORD TABLET, CHEWABLE 4MG	MONTELUKAST ACCORD TABLET, CHEWABLE 4MG	7228/23T, 7229/23T	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
MONTELUKAST ACCORD TABLET, CHEWABLE 5MG	MONTELUKAST ACCORD TABLET, CHEWABLE 5MG	7226/23T, 7227/23T	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
RIASTAP POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	RIASTAP POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	7427/23T	CSL BEHRING GMBH	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
HEMAFERORAL DROPS SOLUTION 50MG/ML	HEMAFERORAL DROPS SOLUTION 50MG/ML	8012/23T, 8013/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of

				the manufacturing process of the finished product - Primary packaging site
PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	7879/23T	BAXTER (HELLAS) EPE	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)
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5 ML	FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5 ML	5897/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.5.a B.I.a.5.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes to the active substance of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza
APIXABAN FARMAPROJECTS TABLET, FILM COATED 2.5MG	APIXABAN FARMAPROJECTS TABLET, FILM COATED 2.5MG	4546/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
APIXABAN FARMAPROJECTS TABLET, FILM COATED 5MG	APIXABAN FARMAPROJECTS TABLET, FILM COATED 5MG	4545/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
HYDROCORTISONE ACTIVASE TABLET 10MG	HYDROCORTISONE ACTIVASE TABLET 10MG	9240/22T	ACTIVASE PHARMACEUTICALS LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
HYDROCORTISONE ACTIVASE TABLET 20MG	HYDROCORTISONE ACTIVASE TABLET 20MG	9239/22T	ACTIVASE PHARMACEUTICALS LTD	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
HYDROCORTISONE ACTIVASE TABLET 10MG	HYDROCORTISONE ACTIVASE TABLET 10MG	7760/20T	ACTIVASE PHARMACEUTICALS LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
HYDROCORTISONE ACTIVASE TABLET 20MG	HYDROCORTISONE ACTIVASE TABLET 20MG	7759/20T	ACTIVASE PHARMACEUTICALS LTD	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Other variation
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 4000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 4000IU	9367/22T, 1133/23T	VENIPHARM	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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 2000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 2000IU	9366/22T, 1134/23T	VENIPHARM	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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 6000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 6000IU	9370/22T, 1137/23T	VENIPHARM	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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 10000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 10000IU	9368/22T, 1135/23T	VENIPHARM	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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 8000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 8000IU	9369/22T, 1136/23T	VENIPHARM	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
LOSARTAN /HYDROCH LOROTHIA ZIDE KRKA TABLET, FILM COATED 50MG/12.5 MG	LOSARTAN /HYDROCH LOROTHIA ZIDE KRKA TABLET, FILM COATED 50MG/12.5 MG	7345/23T, 7346/23T	KRKA D.D. NOVO MESTO	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	LIPITOR TABLET, FILM COATED 10MG	7337/23T, 7338/23T	VIATRIS HELLAS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.I.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
LIPITOR TABLET,	LIPITOR TABLET,	7335/23T, 7336/23T	VIATRIS HELLAS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS

FILM COATED 20MG	FILM COATED 20MG			- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in 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.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
ZARATOR TABLET, FILM COATED 10MG	ZARATOR TABLET, FILM COATED 10MG	7331/23T, 7332/23T	UPJOHN HELLAS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.I.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
LIPITOR TABLET, FILM COATED 40MG	LIPITOR TABLET, FILM COATED 40MG	7333/23T, 7334/23T	VIATRIS HELLAS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.I.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
ZARATOR TABLET, FILM COATED 20MG	ZARATOR TABLET, FILM COATED 20MG	7329/23T, 7330/23T	UPJOHN HELLAS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.I.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
ZARATOR TABLET, FILM COATED 40MG	ZARATOR TABLET, FILM COATED 40MG	7327/23T, 7328/23T	UPJOHN HELLAS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.I.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
LIPITOR TABLET, FILM COATED 20MG	LIPITOR TABLET, FILM COATED 20MG	2745/23T	VIATRIS HELLAS 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
LIPITOR TABLET, FILM COATED 10MG	LIPITOR TABLET, FILM COATED 10MG	2744/23T	VIATRIS HELLAS 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
LIPITOR TABLET, FILM COATED 40MG	LIPITOR TABLET, FILM COATED 40MG	2740/23T	VIATRIS HELLAS 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
ZARATOR TABLET, FILM COATED 10MG	ZARATOR TABLET, FILM COATED 10MG	2738/23T	UPJOHN HELLAS 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
LIPITOR TABLET, CHEWABLE 20MG	LIPITOR TABLET, CHEWABLE 20MG	2742/23T	VIATRIS HELLAS 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
LIPITOR TABLET, CHEWABLE 5MG	LIPITOR TABLET, CHEWABLE 5MG	2739/23T	VIATRIS HELLAS 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
LIPITOR TABLET, CHEWABLE 40MG	LIPITOR TABLET, CHEWABLE 40MG	2741/23T	VIATRIS HELLAS 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
ZARATOR TABLET, FILM COATED 20MG	ZARATOR TABLET, FILM COATED 20MG	2737/23T	UPJOHN HELLAS 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
LIPITOR TABLET, CHEWABLE 10MG	LIPITOR TABLET, CHEWABLE 10MG	2743/23T	VIATRIS HELLAS 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
ZARATOR TABLET, FILM COATED 40MG	ZARATOR TABLET, FILM COATED 40MG	2736/23T	UPJOHN HELLAS 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
CINACALCET/RAFARM TABLET, FILM COATED 60MG	CINACALCET/RAFARM TABLET, FILM COATED 60MG	5764/23T	RAFARM S.A.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
CINACALCET/RAFARM TABLET, FILM COATED 90MG	CINACALCET/RAFARM TABLET, FILM COATED 90MG	5763/23T	RAFARM S.A.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer

				of the active substance supported by an ASMF
CINACALCET/RAFARM TABLET, FILM COATED 30MG	CINACALCET/RAFARM TABLET, FILM COATED 30MG	5765/23T	RAFARM S.A.	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	5061/23T	CASEN RECORDATI SL	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)
MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 4G	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 4G	5060/23T	CASEN RECORDATI SL	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
RIDOCA CAPSULE, HARD 5MG	RIDOCA CAPSULE, HARD 5MG	6224/23T	AENORASIS SA	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
RIDOCA CAPSULE, HARD 140MG	RIDOCA CAPSULE, HARD 140MG	6221/23T	AENORASIS SA	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
RIDOCA CAPSULE, HARD 20MG	RIDOCA CAPSULE, HARD 20MG	6223/23T	AENORASIS SA	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
RIDOCA CAPSULE, HARD 100MG	RIDOCA CAPSULE, HARD 100MG	6222/23T	AENORASIS SA	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
RIDOCA CAPSULE, HARD 180MG	RIDOCA CAPSULE, HARD 180MG	6220/23T	AENORASIS SA	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
RIDOCA CAPSULE, HARD 250MG	RIDOCA CAPSULE, HARD 250MG	6219/23T	AENORASIS SA	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the

				manufacture of the finished product - Other changes
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	6604/23T, 6605/23T	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 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)
ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	6600/23T, 6601/23T	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 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)
ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	6602/23T, 6603/23T	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 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)
ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	6606/23T, 6607/23T	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 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)

VIMETSO TABLET, FILM COATED 50MG/1000 MG	VIMETSO TABLET, FILM COATED 50MG/1000 MG	4202/23T	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
VIMETSO TABLET, FILM COATED 50MG/850MG	VIMETSO TABLET, FILM COATED 50MG/850MG	4203/23T	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
ZYRTEC ORAL SOLUTION 0.1%	ZYRTEC ORAL SOLUTION 0.1%	7920/23T	UCB PHARMA SA	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
CITRAFLEET POWDER FOR ORAL SOLUTION	CITRAFLEET POWDER FOR ORAL SOLUTION	9385/22T	CASEN RECORDATI SL	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND 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	PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	6668/22T	SANOFI PASTEUR.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	6667/22T	SANOFI PASTEUR.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	TETRAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	457/23T	SANOFI PASTEUR.	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
GLICRON MODIFIED-RELEASE TABLET 30MG	GLICRON MODIFIED-RELEASE TABLET 30MG	5409/22T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or

			WIN MEDICA S.A.)	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)
GLICRON MODIFIED-RELEASE TABLET 60MG	GLICRON MODIFIED-RELEASE TABLET 60MG	5408/22T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
LEVOFLOXACIN KABI SOLUTION FOR INFUSION 5MG/ML	LEVOFLOXACIN KABI SOLUTION FOR INFUSION 5MG/ML	5729/23T	FRESENIUS KABI HELLAS AE	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
MYCOPHENOLATE MOFETIL ACCORD TABLET, FILM COATED 500MG	MYCOPHENOLATE MOFETIL ACCORD TABLET, FILM COATED 500MG	3922/23T, 3923/23T, 3924/23T	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	6614/23T, 6615/23T	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	6612/23T, 6613/23T	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	6610/23T, 6611/23T	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier

ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	6608/23T, 6609/23T	ACCORD HEALTHCARE S.L.U	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
ALBUREX 20 SOLUTION FOR INFUSION 200G/L	ALBUREX 20 SOLUTION FOR INFUSION 200G/L	1196/23T, 1197/23T, 1198/23T, 1199/23T, 1200/23T	CSL BEHRING GMBH	B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substanc 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 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 - Second 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 w 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
BREXIN TABLET 20MG	BREXIN TABLET 20MG	6917/23T	CHIESI HELLAS A.E.B.E.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
VIMETSO TABLET, FILM COATED 50MG/1000MG	VIMETSO TABLET, FILM COATED 50MG/1000MG	6452/23T	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
VIMETSO TABLET, FILM COATED 50MG/850MG	VIMETSO TABLET, FILM COATED 50MG/850MG	6453/23T	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
AMOXIL CAPSULE, HARD 500MG	AMOXIL CAPSULE, HARD 500MG	4708/23T, 4709/23T	GLAXOSMITH KLINE (IRELAND) LIMITED	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Minor changes to an approved test procedure
ROSUVAD OR TABLET, FILM COATED 10MG	ROSUVAD OR TABLET, FILM COATED 10MG	6536/23T	TAD PHARMA GMBH	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate
ROSUVAD OR TABLET, FILM COATED 20MG	ROSUVAD OR TABLET, FILM COATED 20MG	6535/23T	TAD PHARMA GMBH	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate
ROSUVAD OR TABLET, FILM COATED 5MG	ROSUVAD OR TABLET, FILM COATED 5MG	6537/23T	TAD PHARMA GMBH	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 100MG	7136/23T	TEVA PHARMA BV	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
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 150MG	7135/23T	TEVA PHARMA BV	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
PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	PALIPERIDONE/TEVA PHARMA PROLONGED RELEASE SUSPENSION FOR INJECTION 75MG	7137/23T	TEVA PHARMA BV	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

GEMCITABINE ACCORD POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	GEMCITABINE ACCORD POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	7794/23T	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	GEMCITABINE ACCORD POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	7793/23T	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
LAMIVUDINE/ZIDOVUDINE ACCORD TABLET, FILM COATED 150MG/300MG	LAMIVUDINE/ZIDOVUDINE ACCORD TABLET, FILM COATED 150MG/300MG	7973/22T	ACCORD HEALTHCARE S.L.U	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
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/500MG	SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/500MG	7325/23T, 7326/23T	APC INSTYTUT SP. Z.O.O.	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)
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/1000MG	SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 50MG/1000MG	7323/23T, 7324/23T	APC INSTYTUT SP. Z.O.O.	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)
SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 100MG/1000MG	SITAGLIPTIN/METFORMIN APC MODIFIED-RELEASE TABLET 100MG/1000MG	7321/23T, 7322/23T	APC INSTYTUT SP. Z.O.O.	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)
NANOGAM SOLUTION FOR INFUSION 100MG/ML	NANOGAM SOLUTION FOR INFUSION 100MG/ML	6756/23T	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
LINEZID SOLUTION FOR	LINEZID SOLUTION FOR	6216/23T	SAPIENS PHARMACEUTICALS LTD	B.I.z B.I.z - Quality change - Active substance - Other variation

INFUSION 2MG/ML	INFUSION 2MG/ML			
MOLAXOLE POWDER FOR ORAL SOLUTION	MOLAXOLE POWDER FOR ORAL SOLUTION	3521/23T	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
MOLAXOLE POWDER FOR ORAL SOLUTION	MOLAXOLE POWDER FOR ORAL SOLUTION	3464/23T	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
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/100MCG	SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/100MCG	6618/23T	GLAXOSMITHKLINE TRADING SERVICES 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
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/500MCG	SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/500MCG	6616/23T	GLAXOSMITHKLINE TRADING SERVICES 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
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/250MCG	SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/250MCG	6617/23T	GLAXOSMITHKLINE TRADING SERVICES 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
SPIRIVA RESPIMAT SOLUTION FOR INHALATION 2.5MCG/PUFF	SPIRIVA RESPIMAT SOLUTION FOR INHALATION 2.5MCG/PUFF	6475/23T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
SPIRIVA INHALATION	SPIRIVA INHALATION	6474/23T	BOEHRINGER INGELHEIM	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a

POWDER, HARD CAPSULE 18MCG	POWDER, HARD CAPSULE 18MCG		INTERNATIONAL GMBH	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
STRIVERDI RESPIMAT SOLUTION FOR INHALATION	STRIVERDI RESPIMAT SOLUTION FOR INHALATION	6476/23T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	SPIOLTO RESPIMAT SOLUTION FOR INHALATION (2.5MCG/2.5MCG)/DOSE	6472/23T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
YANIMO RESPIMAT SOLUTION FOR INHALATION	YANIMO RESPIMAT SOLUTION FOR INHALATION	6473/23T	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G	PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G	6993/23T, 6994/23T, 6995/23T, 6996/23T	FRESENIUS KABI HELLAS A.E.	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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 B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	6997/23T, 6998/23T, 6999/23T, 7000/23T	FRESENIUS KABI HELLAS A.E.	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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 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
VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 1350 PFU	6670/23T, 6671/23T	MERCK SHARP & DOHME BV	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MICROLAX RECTAL SOLUTION (0.45G/0.0645G/4.465G)/DOSE	MICROLAX RECTAL SOLUTION (0.45G/0.0645G/4.465G)/DOSE	7218/23T, 7219/23T, 7220/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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	TESTOGEL TRANSDERMAL GEL 16.2 MG/G	8705/22T, 8706/22T, 8707/22T	LABORATOIRES BESINS INTERNATIONAL	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.5.a A.5.a The activities for which the manufacturer/importer is responsible include batch release
REGAINE WOMEN'S FOAM CUTANEOUS FOAM 5% W/W	REGAINE WOMEN'S FOAM CUTANEOUS FOAM 5% W/W	7428/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VASPIT TABLET, FILM COATED 2MG	VASPIT TABLET, FILM COATED 2MG	7619/23T	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
VASPIT TABLET, FILM COATED 1MG	VASPIT TABLET, FILM COATED 1MG	7620/23T	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
VASPIT TABLET, FILM COATED 4MG	VASPIT TABLET, FILM COATED 4MG	7618/23T	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
OXYNORM SOLUTION FOR INJECTION OR INFUSION 10MG/ML	OXYNORM SOLUTION FOR INJECTION OR INFUSION 10MG/ML	3600/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYCONTIN TABLET, PROLONGED-RELEASE 80MG	OXYCONTIN TABLET, PROLONGED-RELEASE 80MG	3606/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYCONTIN TABLET, PROLONGED-RELEASE 40MG	OXYCONTIN TABLET, PROLONGED-RELEASE 40MG	3605/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYNORM CAPSULE,	OXYNORM CAPSULE,	3608/22T	MUNDIPHARMA	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

HARD 10MG	HARD 10MG		PHARMACEUTICALS LTD	MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYNORM LIQUID ORAL SOLUTION 5MG/5ML	OXYNORM LIQUID ORAL SOLUTION 5MG/5ML	3610/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYCONTIN TABLET, PROLONGED-RELEASE 20MG	OXYCONTIN TABLET, PROLONGED-RELEASE 20MG	3604/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYCONTIN TABLET, PROLONGED-RELEASE 10MG	OXYCONTIN TABLET, PROLONGED-RELEASE 10MG	3603/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYNORM CAPSULE, HARD 5MG	OXYNORM CAPSULE, HARD 5MG	3607/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS,

				or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYNORM SOLUTION FOR INJECTION OR INFUSION 50MG/ML	OXYNORM SOLUTION FOR INJECTION OR INFUSION 50MG/ML	3601/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYNORM CAPSULE, HARD 20MG	OXYNORM CAPSULE, HARD 20MG	3609/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYCONTIN TABLET, PROLONGED-RELEASE 5MG	OXYCONTIN TABLET, PROLONGED-RELEASE 5MG	3602/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH
OXYNORM CONCENTRATE ORAL SOLUTION 10MG/ML	OXYNORM CONCENTRATE ORAL SOLUTION 10MG/ML	3611/22T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.3.b C.I.3.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of change(s) which require to be further

				substantiated by new additional data to be submitted by the MAH
PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 3.86 % W/V/38.6 MG/ML	PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 3.86 % W/V/38.6 MG/ML	3391/23T, 3392/23T, 4427/23T	BAXTER (HELLAS) EPE	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 - Other changes
PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 2.27 % W/V/22.7 MG/ML	PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 2.27 % W/V/22.7 MG/ML	3393/23T, 3394/23T, 4428/23T	BAXTER (HELLAS) EPE	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 - Other changes
PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 1.36 % W/V/13.6 MG/ML	PHYSIONEAL 40 GLUCOSE SOLUTION FOR PERITONEAL DIALYSIS 1.36 % W/V/13.6 MG/ML	3395/23T, 3396/23T, 4429/23T	BAXTER (HELLAS) EPE	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 - Other changes
ACCU-THYROX ORAL SOLUTION 25MCG/5ML	ACCU-THYROX ORAL SOLUTION 25MCG/5ML	758/23T, 759/23T	GALENICA SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ACCU-THYROX ORAL SOLUTION 50MCG/5ML	ACCU-THYROX ORAL SOLUTION 50MCG/5ML	756/23T, 757/23T	GALENICA SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ACCU-THYROX ORAL SOLUTION 100MCG/5 ML	ACCU-THYROX ORAL SOLUTION 100MCG/5 ML	754/23T, 755/23T	GALENICA SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
METFORMIN ACCORD TABLET, FILM COATED 850MG	METFORMIN ACCORD TABLET, FILM COATED 850MG	6821/23T	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
METFORMIN ACCORD TABLET, FILM COATED 500MG	METFORMIN ACCORD TABLET, FILM COATED 500MG	6822/23T	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
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	6467/23T	SANOFI PASTEUR.	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
INFANRIX TETRA SUSPENSION FOR INJECTION	INFANRIX TETRA SUSPENSION FOR INJECTION	7163/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer
BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	BOOSTRIX SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	5785/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
FERANT SOLUTION FOR	FERANT SOLUTION FOR	7902/22T	MEDOCHEMIE LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF

INJECTION 50MCG/ML	INJECTION 50MCG/ML			
AMINOPLASMAL B. BRAUN 10% E SOLUTION FOR INFUSION 100G/L	AMINOPLASMAL B. BRAUN 10% E SOLUTION FOR INFUSION 100G/L	7237/23T, 7238/23T, 7239/23T, 7240/23T, 7241/23T, 7242/23T	B. BRAUN MELSUNGEN AG	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.f B.II.d.2.f - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - To reflect compliance with the Ph.Eur. and remove reference to the outdated internal test method and test method number*
AVAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 160 ANTIGEN UNITS/0.5ML	AVAXIM SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 160 ANTIGEN UNITS/0.5ML	4960/23T, 4961/23T	SANOFI PASTEUR.	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.I.b.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
DAKTARIN CREAM 2% W/W	DAKTARIN CREAM 2% W/W	5648/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SOLIFENACIN ACCORD TABLET, FILM COATED 10MG	SOLIFENACIN ACCORD TABLET, FILM COATED 10MG	7772/23T, 7773/23T	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
SOLIFENACIN ACCORD TABLET, FILM COATED 5MG	SOLIFENACIN ACCORD TABLET, FILM COATED 5MG	7774/23T, 7775/23T	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
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	5558/23T, 5559/23T, 5560/23T	SANOFI PASTEUR.	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.4.c B.I.a.4.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Deletion of a non-significant in-process test B.I.b.z B.I.b.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Other variation
HEXAFLU DAY & NIGHT TABLET 500MG/60MG AND 500MG/25MG	HEXAFLU DAY & NIGHT TABLET 500MG/60MG AND 500MG/25MG	7348/23T, 7349/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	4824/23T, 4825/23T	SANOFI PASTEUR.	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate B.I.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
EFAVIRENZ AUROBINDO TABLET, FILM COATED 600MG	EFAVIRENZ AUROBINDO TABLET, FILM COATED 600MG	7019/23T	AUROBINDO PHARMA (MALTA) LIMITED	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
ADACEL SUSPENSION FOR INJECTION IN PRE-	ADACEL SUSPENSION FOR INJECTION IN PRE-	3920/23T	SANOFI PASTEUR.	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

FILLED SYRINGE	FILLED SYRINGE			in the manufacture of the finished product - Minor change in the manufacturing process
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	5557/23T	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
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	2595/23T	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 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
ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	ADACEL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	3522/23T, 3523/23T, 3524/23T	SANOFI PASTEUR.	B.I.b.2.b B.I.b.2.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Deletion of a test procedure for the active substance or a starting material/reagent/ intermediate, if an alternative test procedure is already authorised. B.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
CYTARABINE ACCORD SOLUTION FOR INJECTION OR INFUSION 100MG/ML	CYTARABINE ACCORD SOLUTION FOR INJECTION OR INFUSION 100MG/ML	7207/23T	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)*
ALBUMAN SOLUTION FOR INFUSION 40G/L	ALBUMAN SOLUTION FOR INFUSION 40G/L	6876/23T	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	ALBUMAN SOLUTION FOR	6875/23T	PROTHYA BIOSOLUTIONS	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other

INFUSION 200G/L	INFUSION 200G/L		NETHERLANDS B.V.	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
ZIRCOS TABLET, FILM COATED 10MG	ZIRCOS TABLET, FILM COATED 10MG	1238/23T, 1239/23T, 1240/23T, 1241/23T	NASSINGTON LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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.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
ZIRCOS TABLET, FILM COATED 5MG	ZIRCOS TABLET, FILM COATED 5MG	1242/23T, 1243/23T, 1244/23T, 1245/23T	NASSINGTON LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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.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
ZIRCOS TABLET, FILM COATED 20MG	ZIRCOS TABLET, FILM COATED 20MG	1234/23T, 1235/23T, 1236/23T, 1237/23T	NASSINGTON LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an 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.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
ZIRCOS TABLET, FILM COATED 10MG	ZIRCOS TABLET, FILM COATED 10MG	7789/23T, 7790/23T	NASSINGTON LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZIRCOS TABLET, FILM COATED 5MG	ZIRCOS TABLET, FILM COATED 5MG	7791/23T, 7792/23T	NASSINGTON LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ZIRCOS TABLET, FILM	ZIRCOS TABLET, FILM	7787/23T, 7788/23T	NASSINGTON LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product,

COATED 20MG	COATED 20MG			packaging site, manufacturer 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
PANADOL COLD & FLU & COUGH POWDER FOR ORAL SOLUTION 1000MG/200MG/12.2MG	PANADOL COLD & FLU & COUGH POWDER FOR ORAL SOLUTION 1000MG/200MG/12.2MG	3221/20T, 3222/20T, 3223/20T	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.III.1 a) 2. Updated certificate from an already approved manufacturer A.5 a) The activities for which the manufacturer/importer is responsible include batch release
PANADOL COLD & FLU & COUGH CAPSULE, HARD 500MG/100MG/6.1MG	PANADOL COLD & FLU & COUGH CAPSULE, HARD 500MG/100MG/6.1MG	5599/23T, 5600/23T, 5601/23T	GLAXOSMITH KLINE 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PANADOL COLD & FLU & COUGH POWDER FOR ORAL SOLUTION 1000MG/200MG/12.2MG	PANADOL COLD & FLU & COUGH POWDER FOR ORAL SOLUTION 1000MG/200MG/12.2MG	5602/23T, 5603/23T, 5604/23T	GLAXOSMITH KLINE 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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,	MOXILEN CAPSULE,	7808/23T	MEDOCHEMIE LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing

HARD 250MG	HARD 250MG			sites for an active substance, intermediate or finished product, packaging site, manufacturer 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	MOXILEN CAPSULE, HARD 500MG	7807/23T	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)*
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	7148/23T, 7149/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer
PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	PRIORIX-TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	7150/23T, 7151/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer
PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE-FILLED SYRINGE	7152/23T, 7153/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer
LOSARTAN /HYDROCH LOROTHIA ZIDE KRKA TABLET, FILM	LOSARTAN /HYDROCH LOROTHIA ZIDE KRKA TABLET, FILM	6182/23T, 6183/23T	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

COATED 100/12.5MG	COATED 100/12.5MG			medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
ZANERIL TABLET, FILM COATED 10MG/10MG	ZANERIL TABLET, FILM COATED 10MG/10MG	7223/23T	RECORDATI HELLAS PHARMACEUTICALS SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ZANERIL TABLET, FILM COATED 20MG/10MG	ZANERIL TABLET, FILM COATED 20MG/10MG	7222/23T	RECORDATI HELLAS PHARMACEUTICALS SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ZANERIL TABLET, FILM COATED 20MG/20MG	ZANERIL TABLET, FILM COATED 20MG/20MG	7221/23T	RECORDATI HELLAS PHARMACEUTICALS SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ZOVIDUO CREAM (50MG/10MG)/G	ZOVIDUO CREAM (50MG/10MG)/G	3720/23T	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	OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	3719/23T	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

NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	NICORETTE QUICKSPRAY BERRY OROMUCOSAL SPRAY, SOLUTION 1MG/SPRAY	5936/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes
CONTRACTUBEX GEL	CONTRACTUBEX GEL	7746/23T	MERZ PHARMACEUTICALS GMBH	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
MOXIFALON T TABLET, FILM COATED 400MG	MOXIFALON T TABLET, FILM COATED 400MG	1633/21T	DEMO 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
SUGAMMADEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	SUGAMMADEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	7320/23T	SAPIENS PHARMACEUTICALS LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
COTROVAL TABLET, FILM COATED 80/12.5MG	COTROVAL TABLET, FILM COATED 80/12.5MG	7644/23T	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
COTROVAL TABLET, FILM COATED 320/12.5MG	COTROVAL TABLET, FILM COATED 320/12.5MG	7641/23T	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
COTROVAL TABLET, FILM COATED 160/25MG	COTROVAL TABLET, FILM COATED 160/25MG	7642/23T	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
COTROVAL TABLET, FILM COATED 320/25MG	COTROVAL TABLET, FILM COATED 320/25MG	7640/23T	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
COTROVAL TABLET, FILM COATED 160/12.5MG	COTROVAL TABLET, FILM COATED 160/12.5MG	7643/23T	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
NOSATEL TABLET, FILM COATED 25MG	NOSATEL TABLET, FILM COATED 25MG	3731/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SIMEVIN TABLET, FILM COATED 50MG/1000MG	SIMEVIN TABLET, FILM COATED 50MG/1000MG	6588/23T, 6589/23T, 6590/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological s
SIMEVIN TABLET, FILM COATED 50MG/850MG	SIMEVIN TABLET, FILM COATED 50MG/850MG	6591/23T, 6592/23T, 6593/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL	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

			LABORATORIES SA	substance - Up to 10-fold increase compared to the originally approved batch size B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological s
TAPTIQOM EYE DROPS, SOLUTION (15MCG/5MG)/ML	TAPTIQOM EYE DROPS, SOLUTION (15MCG/5MG)/ML	5549/23T	VIANEX S.A	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
TAPTIQOM EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (15MCG/5MG)/ML	TAPTIQOM EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (15MCG/5MG)/ML	5551/23T	VIANEX S.A	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
SAFLUTAN EYE DROPS, SOLUTION 15MCG/ML	SAFLUTAN EYE DROPS, SOLUTION 15MCG/ML	5550/23T	VIANEX S.A	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
TAFLOTAN EYE DROPS, SOLUTION 15MCG/ML	TAFLOTAN EYE DROPS, SOLUTION 15MCG/ML	5552/23T	VIANEX S.A	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
CEZID POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	CEZID POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	6880/23T	SAPIENS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
DAREQ TABLET, FILM COATED 5MG	DAREQ TABLET, FILM COATED 5MG	5004/23T	DELORBIS PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
ADACEL SUSPENSION FOR INJECTION IN PRE-	ADACEL SUSPENSION FOR INJECTION IN PRE-	4977/23T	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

FILLED SYRINGE	FILLED SYRINGE			primary packaging - Device with CE marking
ZOVIDUO CREAM (50MG/10MG)/G	ZOVIDUO CREAM (50MG/10MG)/G	5715/23T	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
PANMIGRAN TABLET, FILM COATED 250MG/250MG/65MG	PANMIGRAN TABLET, FILM COATED 250MG/250MG/65MG	5712/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PANADOL COLD & FLU & COUGH CAPSULE, HARD 500MG/100MG/6.1MG	PANADOL COLD & FLU & COUGH CAPSULE, HARD 500MG/100MG/6.1MG	5714/23T	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	OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	5713/23T	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
LUCIDEL TABLET, FILM COATED 150MG	LUCIDEL TABLET, FILM COATED 150MG	4718/22T	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 C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LUCIDEL TABLET, FILM	LUCIDEL TABLET, FILM	4719/22T	ELPEN PHARMACEUTICAL CO INC	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)

COATED 75MG	COATED 75MG			in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LUCIDEL TABLET, FILM COATED 300MG	LUCIDEL TABLET, FILM COATED 300MG	4717/22T	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 C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ADVECIT CAPSULE, HARD 100MG	ADVECIT CAPSULE, HARD 100MG	7648/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
ADVECIT CAPSULE, HARD 180MG	ADVECIT CAPSULE, HARD 180MG	7646/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
ADVECIT CAPSULE, HARD 140MG	ADVECIT CAPSULE, HARD 140MG	7647/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
ADVECIT CAPSULE, HARD 250MG	ADVECIT CAPSULE, HARD 250MG	7645/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
ADVECIT CAPSULE, HARD 20MG	ADVECIT CAPSULE, HARD 20MG	7649/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes

ADVECIT CAPSULE, HARD 5MG	ADVECIT CAPSULE, HARD 5MG	7650/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	6005/23T	SANOFI PASTEUR.	B.I.a.5.a B.I.a.5.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes to the active substance of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza
OLMESARTAN TAD TABLET, FILM COATED 20MG	OLMESARTAN TAD TABLET, FILM COATED 20MG	1950/22T	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
OLMESARTAN TAD TABLET, FILM COATED 10MG	OLMESARTAN TAD TABLET, FILM COATED 10MG	1949/22T	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
OLMESARTAN TAD TABLET, FILM COATED 40MG	OLMESARTAN TAD TABLET, FILM COATED 40MG	1951/22T	TAD PHARMA GMBH	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change)
FLUDARABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTION 25MG/ML	FLUDARABINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTION 25MG/ML	6488/23T	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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	5207/23T, 5208/23T, 5209/23T	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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	5204/23T, 5205/23T, 5206/23T	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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	5210/23T, 5211/23T, 5212/23T	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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 2MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 2MG	5216/23T, 5217/23T, 5218/23T	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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	5213/23T, 5214/23T, 5215/23T	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
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	5201/23T, 5202/23T, 5203/23T	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
ADVECIT CAPSULE, HARD 250MG	ADVECIT CAPSULE, HARD 250MG	7623/23T	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
ADVECIT CAPSULE, HARD 180MG	ADVECIT CAPSULE, HARD 180MG	7624/23T	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
ADVECIT CAPSULE, HARD 140MG	ADVECIT CAPSULE, HARD 140MG	7625/23T	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
ADVECIT CAPSULE, HARD 100MG	ADVECIT CAPSULE, HARD 100MG	7626/23T	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*

ADVECIT CAPSULE, HARD 20MG	ADVECIT CAPSULE, HARD 20MG	7627/23T	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
ADVECIT CAPSULE, HARD 5MG	ADVECIT CAPSULE, HARD 5MG	7628/23T	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*
CREDANIL TABLET 100MG/25MG	CREDANIL TABLET 100MG/25MG	7394/23T	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
CREDANIL TABLET 100MG/10MG	CREDANIL TABLET 100MG/10MG	7395/23T	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
CREDANIL TABLET 250MG/25MG	CREDANIL TABLET 250MG/25MG	7393/23T	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
SODIUM CHLORIDE/ DEMO SOLUTION FOR INTRAVENOUS INFUSION 0.9% W/V	SODIUM CHLORIDE/ DEMO SOLUTION FOR INTRAVENOUS INFUSION 0.9% W/V	6260/23T	THE STAR MEDICINES IMPORTERS CO. LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation

MONTOL TABLET, CHEWABLE 5MG	MONTOL TABLET, CHEWABLE 5MG	7606/23T	DELORBIS PHARMACEUTICALS 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
MONTOL TABLET, CHEWABLE 4MG	MONTOL TABLET, CHEWABLE 4MG	7607/23T	DELORBIS PHARMACEUTICALS 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
MONTOL TABLET, FILM COATED 10MG	MONTOL TABLET, FILM COATED 10MG	7605/23T	DELORBIS PHARMACEUTICALS 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
FELDENE TABLET, DISPERSIBLE 20MG	FELDENE TABLET, DISPERSIBLE 20MG	6454/23T	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
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 50U	BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 50U	6758/23T	MERZ PHARMACEUTICALS GMBH	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 100U	BOCOUTURE POWDER FOR SOLUTION FOR INJECTION 100U	6757/23T	MERZ PHARMACEUTICALS GMBH	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
KABIVIT ORAL DROPS SOLUTION 14.400 IU/ML	KABIVIT ORAL DROPS SOLUTION 14.400 IU/ML	6211/23T	FRESENIUS KABI 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	TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	1725/23T, 1726/23T	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 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	1719/23T, 1720/23T	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 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	1721/23T, 1722/23T	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 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	1723/23T, 1724/23T	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 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/VIAL (100IU/ML)	OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU/VIAL (100IU/ML)	5880/23T, 5881/23T	OCTAPHARMA (IP) SPRL	B.II.h.1.b.1 B.II.h.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Adventitious Agents Safety - Update to the “Adventitious Agents Safety Evaluation” information (section 3.2.A.2) - Replacement of obsolete studies related to manufacturing steps and adventitious agents already reported in the dossier - with modification of risk assessment 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
OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/VIAL(100IU/ML)	OCTANINE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU/VIAL(100IU/ML)	5878/23T, 5879/23T	OCTAPHARMA (IP) SPRL	B.II.h.1.b.1 B.II.h.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Adventitious Agents Safety - Update to the “Adventitious Agents Safety Evaluation” information (section 3.2.A.2) - Replacement of obsolete studies related to manufacturing steps and adventitious agents already reported in the dossier - with modification of risk assessment 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
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	7172/23T	MEDOCHEMIE LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	7171/23T	MEDOCHEMIE LTD	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
SOLPADEINE SOLUBLE TABLET	SOLPADEINE SOLUBLE TABLET	7736/23T	OMEGA PHARMA HELLAS S.A	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active

				substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ABIRATERONE/SANDOZ TABLET, FILM COATED 500MG	ABIRATERONE/SANDOZ TABLET, FILM COATED 500MG	6990/23T	SANDOZ PHARMACEUTICALS D.D.	B.II.b).1. a) Secondary packaging site variation Type IAIN (B.II.b.1.a): to add Logifarma S.r.l, Via Campobello 1, 00071 Pomezia, Italy as an alternative site responsible for secondary packaging of the finished product.
BORTEZOMIB/TEVA POWDER FOR SOLUTION FOR INJECTION 3.5MG/VIAL	BORTEZOMIB/TEVA POWDER FOR SOLUTION FOR INJECTION 3.5MG/VIAL	6836/23T, 6837/23T	TEVA BV	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information B.II.e.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
CURILEN CAPSULE, HARD 10MG/75MG	CURILEN CAPSULE, HARD 10MG/75MG	6490/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CURILEN CAPSULE, HARD 5MG/100MG	CURILEN CAPSULE, HARD 5MG/100MG	6491/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CURILEN CAPSULE, HARD 5MG/75MG	CURILEN CAPSULE, HARD 5MG/75MG	6489/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EDEVIRA TABLET, FILM COATED 1MG	EDEVIRA TABLET, FILM COATED 1MG	6492/23T	PHARMATHEN S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
EDEVIRA TABLET, FILM COATED 0.5MG	EDEVIRA TABLET, FILM COATED 0.5MG	6493/23T	PHARMATHEN S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active

				substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	OCTAGAM SOLUTION FOR INFUSION 50MG/ML	7035/23T	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
OCTAGAM SOLUTION FOR INFUSION 10%	OCTAGAM SOLUTION FOR INFUSION 10%	7036/23T	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
YASMINELLE TABLET, FILM COATED 0.02MG/3MG	YASMINELLE TABLET, FILM COATED 0.02MG/3MG	1441/23T	BAYER HELLAS ABEE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
EFAVIRENZ AUROBINDO TABLET, FILM COATED 600MG	EFAVIRENZ AUROBINDO TABLET, FILM COATED 600MG	6324/23T	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
AMOXAPEN CAPSULE, HARD 250MG	AMOXAPEN CAPSULE, HARD 250MG	7604/23T	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
AMOXAPEN CAPSULE,	AMOXAPEN CAPSULE,	7603/23T	REMEDICA LTD	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in

HARD 500MG	HARD 500MG			the specification parameters and/or limits of the finished product - Other changes
METOCLOPRAMIDE ACCORD TABLET 10MG	METOCLOPRAMIDE ACCORD TABLET 10MG	6089/23T	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
METOCLOPRAMIDE ACCORD TABLET 10MG	METOCLOPRAMIDE ACCORD TABLET 10MG	6345/23T	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
HEXALEN OROMUCOSAL SPRAY 0.2%	HEXALEN OROMUCOSAL SPRAY 0.2%	7680/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PARACETAMOL ACCORD SOLUTION FOR INFUSION 10MG/ML	PARACETAMOL ACCORD SOLUTION FOR INFUSION 10MG/ML	3972/22T	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 + QRD update
ROSUVADOR TABLET, FILM COATED 5MG	ROSUVADOR TABLET, FILM COATED 5MG	5536/23T, 5537/23T	TAD PHARMA GMBH	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - 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)

ROSUVAD OR TABLET, FILM COATED 20MG	ROSUVAD OR TABLET, FILM COATED 20MG	5532/23T, 5533/23T	TAD PHARMA GMBH	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - 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)
ROSUVAD OR TABLET, FILM COATED 10MG	ROSUVAD OR TABLET, FILM COATED 10MG	5534/23T, 5535/23T	TAD PHARMA GMBH	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - 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)
ADDAMEL N NEW CONCENT RATE FOR SOLUTION FOR INFUSION	ADDAMEL N NEW CONCENT RATE FOR SOLUTION FOR INFUSION	7154/23T	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
STATOL TABLET, FILM COATED 20MG	STATOL TABLET, FILM COATED 20MG	7079/23T	DELORBIS PHARMACEU TICALS 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

STATOL TABLET, FILM COATED 10MG	STATOL TABLET, FILM COATED 10MG	7080/23T	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
STATOL TABLET, FILM COATED 5MG	STATOL TABLET, FILM COATED 5MG	7081/23T	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
STATOL TABLET, FILM COATED 40MG	STATOL TABLET, FILM COATED 40MG	7078/23T	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
HEXALEN OROMUCOSAL SOLUTION 5MG/5ML	HEXALEN OROMUCOSAL SOLUTION 5MG/5ML	7679/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ABIRATERONE SAPIENS TABLET, FILM COATED 500MG	ABIRATERONE SAPIENS TABLET, FILM COATED 500MG	7271/23T, 7272/23T, 7273/23T, 7274/23T	SAPIENS PHARMACEUTICALS 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 B.I.b.2.c B.I.b.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for a reagent, which does

				not have a significant effect on the overall quality of the active substance
AMLODIPIN ACCORD TABLET 10MG	AMLODIPIN ACCORD TABLET 10MG	6201/23T, 6202/23T	ACCORD HEALTHCARE S.L.U	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.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
AMLODIPIN ACCORD TABLET 5MG	AMLODIPIN ACCORD TABLET 5MG	6203/23T, 6204/23T	ACCORD HEALTHCARE S.L.U	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.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
SRIVASSO INHALATIO N POWDER, HARD CAPSULE 18MCG	SRIVASSO INHALATIO N POWDER, HARD CAPSULE 18MCG	6741/23T	BOEHRINGER INGELHEIM INTERNATION AL GMBH	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
MERONEM POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	MERONEM POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	6986/23T, 6987/23T	PFIZER HELLAS AE	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release A.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)
AMOXIL FORTE POWDER	AMOXIL FORTE POWDER	1935/23T, 1936/23T, 1937/23T	GLAXOSMITH KLINE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

FOR ORAL SUSPENSION 250MG/5ML	FOR ORAL SUSPENSION 250MG/5ML		(IRELAND) LIMITED	Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer
OMPRANYT GASTRO-RESISTANT CAPSULE, HARD 20MG	OMPRANYT GASTRO-RESISTANT CAPSULE, HARD 20MG	7616/23T	BIAL-PORTELA & CA, SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	6178/23T, 6179/23T	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 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.
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED	LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED	6180/23T, 6181/23T	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

50MG/12.5 MG	50MG/12.5 MG			assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
ULTRAVIST 370 SOLUTION FOR INJECTION 76.9%	ULTRAVIST 370 SOLUTION FOR INJECTION 76.9%	140/23T	BAYER HELLAS ABEE	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ULTRAVIST 300 SOLUTION FOR INJECTION 62.34%	ULTRAVIST 300 SOLUTION FOR INJECTION 62.34%	141/23T	BAYER HELLAS ABEE	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
WATER FOR INJECTION SOLVENT FOR PARENTERAL USE 100% W/V	WATER FOR INJECTION SOLVENT FOR PARENTERAL USE 100% W/V	6726/23T, 6727/23T	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 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)
ADVANTAN CREAM 0.1% (W/W)	ADVANTAN CREAM 0.1% (W/W)	6238/23T, 6239/23T, 6240/23T, 6241/23T, 6242/23T, 6243/23T, 6244/23T, 6245/23T, 6246/23T, 6247/23T, 6248/23T, 6249/23T, 6250/23T, 6251/23T, 6252/23T	LEO PHARMA A/S	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 B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or star B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or star B.I.b.1.f B.I.b.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or 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 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 star B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediat
LACOSADEL TABLET, FILM COATED 200MG	LACOSADEL TABLET, FILM COATED 200MG	7575/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LACOSADEL TABLET, FILM COATED 150MG	LACOSADEL TABLET, FILM COATED 150MG	7576/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LACOSADEL TABLET, FILM COATED 100MG	LACOSADEL TABLET, FILM COATED 100MG	7577/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LACOSADEL TABLET, FILM COATED 50MG	LACOSADEL TABLET, FILM COATED 50MG	7578/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished

				product - Minor change in the manufacturing process
DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01 MG/ML	DENTOCAINE SOLUTION FOR INJECTION 40MG/0.01 MG/ML	6857/23T	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/0.005 MG/ML	DENTOCAINE SOLUTION FOR INJECTION 40MG/0.005 MG/ML	6856/23T	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
LIOTON 1000 GEL 100000IU/100G	LIOTON 1000 GEL 100000IU/100G	7187/22T, 367/23T	A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE SRL	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.II.a.z B.II.a.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Other variation
FLUXIL CAPSULE, HARD 20MG	FLUXIL CAPSULE, HARD 20MG	7429/23T	DELORBIS PHARMACEUTICALS LTD	B.II.d.1.g B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue
WATER FOR INJECTION SOLVENT FOR PARENTERAL USE 100% W/V	WATER FOR INJECTION SOLVENT FOR PARENTERAL USE 100% W/V	6587/23T	THE STAR MEDICINES IMPORTERS CO. LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ZOVIDUO CREAM (50MG/10MG)/G	ZOVIDUO CREAM (50MG/10MG)/G	3722/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	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
OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	3721/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ	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

			ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	activities for which the manufacturer/importer is responsible include batch release
SALOFALK SUPPOSITORY 1G	SALOFALK SUPPOSITORY 1G	2010/23T	DR. FALK PHARMA GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP
VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	VINCRISTINE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	7084/23T, 7085/23T	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 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
OCTAGAM SOLUTION FOR INFUSION 10%	OCTAGAM SOLUTION FOR INFUSION 10%	5071/23T, 5072/23T	OCTAPHARMA (IP) SPRL	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.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
CASPOFUNGIN DEMO POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 50MG/VIAL	CASPOFUNGIN DEMO POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 50MG/VIAL	6828/22T	DEMO S.A.	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
CASPOFUNGIN DEMO POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 70MG/VIAL	CASPOFUNGIN DEMO POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 70MG/VIAL	6827/22T	DEMO S.A.	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
PAROXETINE AUROBINDO TABLET, FILM	PAROXETINE AUROBINDO TABLET, FILM	3285/23T	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

COATED 20MG	COATED 20MG			Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PAROXETINE AUROBINDO TABLET, FILM COATED 30MG	PAROXETINE AUROBINDO TABLET, FILM COATED 30MG	3284/23T	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
BRUFEDOL TABLET, FILM COATED 600MG	BRUFEDOL TABLET, FILM COATED 600MG	6598/23T	VIATRIS HEALTHCARE LIMITED.	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
BRUFEDOL TABLET, FILM COATED 400MG	BRUFEDOL TABLET, FILM COATED 400MG	6599/23T	VIATRIS HEALTHCARE LIMITED.	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	OCTAGAM SOLUTION FOR INFUSION 50MG/ML	5073/23T, 5074/23T	OCTAPHARMA (IP) SPRL	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.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
FLUNOL CAPSULE, HARD 100MG	FLUNOL CAPSULE, HARD 100MG	7496/23T	PHARMA Q AE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
VENLAFAXIN TAD CAPSULE, HARD, PROLONGED-RELEASE 150MG	VENLAFAXIN TAD CAPSULE, HARD, PROLONGED-RELEASE 150MG	3576/23T, 3577/23T	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS,

				or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
VENLAFAXIN TAD CAPSULE, HARD, PROLONGED-RELEASE 75MG	VENLAFAXIN TAD CAPSULE, HARD, PROLONGED-RELEASE 75MG	3578/23T, 3579/23T	TAD PHARMA GMBH	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 5MG/ML	MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 5MG/ML	6920/23T	B. BRAUN MELSUNGEN AG	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 1MG/ML	MIDAZOLAM B. BRAUN SOLUTION FOR INJECTION OR INFUSION 1MG/ML	6921/23T	B. BRAUN MELSUNGEN AG	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority
EREZEL TABLET 10MG	EREZEL TABLET 10MG	7419/21T, 7420/21T	VENIFAR 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FLAGYL TABLET 400MG	FLAGYL TABLET 400MG	358/23T	SANOFI WINTHROP INDUSTRIE.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of an agreed wording, no new data submitted
CERTICAN TABLET 1MG	CERTICAN TABLET 1MG	5522/23T, 5523/23T, 5524/23T	NOVARTIS 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 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
CERTICAN TABLET 0.5MG	CERTICAN TABLET 0.5MG	5516/23T, 5517/23T, 5518/23T	NOVARTIS 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 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
CERTICAN TABLET 0.75MG	CERTICAN TABLET 0.75MG	5513/23T, 5514/23T, 5515/23T	NOVARTIS 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 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
CERTICAN TABLET 0.25MG	CERTICAN TABLET 0.25MG	5519/23T, 5520/23T, 5521/23T	NOVARTIS 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 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
MENOPUR SOLUTION FOR INJECTION IN A PRE-FILLED PEN 600IU	MENOPUR SOLUTION FOR INJECTION IN A PRE-FILLED PEN 600IU	5498/23T	FERRING HELLAS MEPE	B.IV.1.z B.IV.1.z - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Other variation
MENOPUR SOLUTION FOR INJECTION IN A PRE-FILLED PEN 1200IU	MENOPUR SOLUTION FOR INJECTION IN A PRE-FILLED PEN 1200IU	5497/23T	FERRING HELLAS MEPE	B.IV.1.z B.IV.1.z - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Other variation
MEDSAMIC SOLUTION FOR INJECTION 100MG/ML	MEDSAMIC SOLUTION FOR INJECTION 100MG/ML	5784/23T	MEDOCHEMIE LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
MAYMETSI TABLET, FILM COATED 50MG/1000 MG	MAYMETSI TABLET, FILM COATED 50MG/1000 MG	6387/23T	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
MAYMETSI TABLET, FILM COATED 50MG/850MG	MAYMETSI TABLET, FILM COATED 50MG/850MG	6386/23T	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
SANDOSTATIN LAR POWDER AND SOLVENT	SANDOSTATIN LAR POWDER AND SOLVENT	6384/23T	NOVARTIS IRELAND LIMITED	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or

FOR SUSPENSION FOR INJECTION 20MG	FOR SUSPENSION FOR INJECTION 20MG			devices (when mentioned in the dossier) - Replacement or addition of a supplier
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 30MG	SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 30MG	6383/23T	NOVARTIS IRELAND LIMITED	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 10MG	SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 10MG	6385/23T	NOVARTIS IRELAND LIMITED	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
FYLEPSIA TABLET, FILM COATED 4MG	FYLEPSIA TABLET, FILM COATED 4MG	5683/23T	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
FYLEPSIA TABLET, FILM COATED 2MG	FYLEPSIA TABLET, FILM COATED 2MG	5684/23T	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
FYLEPSIA TABLET, FILM COATED 6MG	FYLEPSIA TABLET, FILM COATED 6MG	5682/23T	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
FYLEPSIA TABLET, FILM	FYLEPSIA TABLET, FILM	5680/23T	ELPEN PHARMACEUTICAL CO INC	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

COATED 10MG	COATED 10MG			MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
FYLEPSIA TABLET, FILM COATED 8MG	FYLEPSIA TABLET, FILM COATED 8MG	5681/23T	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
FYLEPSIA TABLET, FILM COATED 12MG	FYLEPSIA TABLET, FILM COATED 12MG	5679/23T	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
ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	4498/23T	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
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	4497/23T	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
ROSUVASTATIN ACCORD TABLET, FILM	ROSUVASTATIN ACCORD TABLET, FILM	4496/23T	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

COATED 20MG	COATED 20MG			Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 ACCORD TABLET, FILM COATED 40MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	4495/23T	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
MAYMETSI TABLET, FILM COATED 50MG/1000 MG	MAYMETSI TABLET, FILM COATED 50MG/1000 MG	3853/23T	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)
MAYMETSI TABLET, FILM COATED 50MG/850MG	MAYMETSI TABLET, FILM COATED 50MG/850MG	3852/23T	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)
TRACRIUM INJECTION 10MG/ML	TRACRIUM INJECTION 10MG/ML	3824/23T	ASPEN PHARMA TRADING 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
ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 40MG	ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 40MG	733/23T	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
ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 20MG	ESOMEPRAZOLE KRKA GASTRO-RESISTANT CAPSULE, HARD 20MG	734/23T	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

VILDAGLIPTIN ACCORD TABLET 50MG	VILDAGLIPTIN ACCORD TABLET 50MG	4452/23T	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
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 20MG	SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 20MG	6192/23T	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)
SANDOSTATIN SOLUTION FOR INJECTION & INFUSION 0.1MG/ML	SANDOSTATIN SOLUTION FOR INJECTION & INFUSION 0.1MG/ML	6194/23T	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)
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 10MG	SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 10MG	6193/23T	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)
SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 30MG	SANDOSTATIN LAR POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION 30MG	6191/23T	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)

VINORELBINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	VINORELBINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	6389/23T	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
CERTICAN TABLET 1MG	CERTICAN TABLET 1MG	6969/23T, 6970/23T, 6971/23T	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release 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)
CERTICAN TABLET 0.5MG	CERTICAN TABLET 0.5MG	6963/23T, 6964/23T, 6965/23T	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release 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)
CERTICAN TABLET 0.75MG	CERTICAN TABLET 0.75MG	6960/23T, 6961/23T, 6962/23T	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release 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)
CERTICAN TABLET 0.25MG	CERTICAN TABLET 0.25MG	6966/23T, 6967/23T, 6968/23T	NOVARTIS IRELAND LIMITED	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release 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)
ATAZANAVIR ACCORD CAPSULE, HARD 150MG	ATAZANAVIR ACCORD CAPSULE, HARD 150MG	4473/23T	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
ATAZANAVIR ACCORD CAPSULE, HARD 300MG	ATAZANAVIR ACCORD CAPSULE, HARD 300MG	4472/23T	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
MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG	MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG	1480/23T, 1481/23T, 1482/23T, 1483/23T, 1484/23T, 1485/23T, 1486/23T	MEDOCHEMIE 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 - Change in the specification parameters and/or limits of the finished product to more accurately describe the appearance of the drug product B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product -

				Other changes to a test procedure (including replacement or addition) B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	1473/23T, 1474/23T, 1475/23T, 1476/23T, 1477/23T, 1478/23T, 1479/23T	MEDOCHEMIE 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 - Change in the specification parameters and/or limits of the finished product to more accurately describe the appearance of the drug product B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	1466/23T, 1467/23T, 1468/23T, 1469/23T, 1470/23T, 1471/23T, 1472/23T	MEDOCHEMIE 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 - Change in the specification parameters and/or limits of the finished product to more accurately describe the appearance of the drug product B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or

				limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG	MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG	1489/23T	MEDOCHEMIE LTD	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
MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	1488/23T	MEDOCHEMIE LTD	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
MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	MONOCLOX POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	1487/23T	MEDOCHEMIE LTD	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
GENEMENT TABLET, FILM COATED 20MG	GENEMENT TABLET, FILM COATED 20MG	441/21T	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
GENEMENT TABLET, FILM COATED 5MG	GENEMENT TABLET, FILM COATED 5MG	442/21T	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
COLMIFEN TABLET 10MG	COLMIFEN TABLET 10MG	7406/23T, 7407/23T, 7408/23T	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DAPTOMYCIN NORIDEM	DAPTOMYCIN NORIDEM	5802/23T	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

POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL			storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
DAPTOMYCIN NORIDEM POWDER FOR SOLUTION FOR INJECTION /INFUSION 350MG/VIAL	DAPTOMYCIN NORIDEM POWDER FOR SOLUTION FOR INJECTION /INFUSION 350MG/VIAL	5803/23T	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)
OCTAGAM SOLUTION FOR INFUSION 10%	OCTAGAM SOLUTION FOR INFUSION 10%	2469/23T, 2470/23T, 2471/23T, 2472/23T	OCTAPHARMA (IP) SPRL	B.I.a.3.c B.I.a.3.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The change requires assessment 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.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.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
TACROLIMUS ACCORD OINTMENT 0.1%	TACROLIMUS ACCORD OINTMENT 0.1%	7146/23T, 7147/23T	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 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
DEXETA EYE DROPS, SOLUTION 1.5MG/ML	DEXETA EYE DROPS, SOLUTION 1.5MG/ML	6255/23T	SIFI S.P.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
SIMEVIN TABLET, FILM COATED 50MG/850MG	SIMEVIN TABLET, FILM COATED 50MG/850MG	6184/23T	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
SIMEVIN TABLET, FILM COATED 50MG/1000MG	SIMEVIN TABLET, FILM COATED 50MG/1000MG	6185/23T	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
SOLIFENACIN SANDOZ TABLET, FILM COATED 5MG	SOLIFENACIN SANDOZ TABLET, FILM COATED 5MG	6645/23T, 6646/23T, 6647/23T, 6648/23T, 6649/23T, 6650/23T	SANDOZ GMBH	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
SOLIFENACIN SANDOZ TABLET, FILM COATED 10MG	SOLIFENACIN SANDOZ TABLET, FILM COATED 10MG	6639/23T, 6640/23T, 6641/23T, 6642/23T, 6643/23T, 6644/23T	SANDOZ GMBH	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	5069/22T	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
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	5068/22T	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
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	9251/22T, 9252/22T, 9253/22T	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 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)*
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	9248/22T, 9249/22T, 9250/22T	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 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)*
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	5092/22T	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
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE,	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE,	5091/22T	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

HARD 60MG	HARD 60MG			assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	7930/20T	ACCORD HEALTHCARE S.L.U	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	7929/20T	ACCORD HEALTHCARE S.L.U	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
CURILEN CAPSULE, HARD 10MG/75MG	CURILEN CAPSULE, HARD 10MG/75MG	6394/23T, 6395/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* 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
CURILEN CAPSULE, HARD 5MG/100MG	CURILEN CAPSULE, HARD 5MG/100MG	6398/23T, 6399/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* 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
CURILEN CAPSULE, HARD 10MG/100MG	CURILEN CAPSULE, HARD 10MG/100MG	6396/23T, 6397/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* 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
CURILEN CAPSULE, HARD 5MG/75MG	CURILEN CAPSULE, HARD 5MG/75MG	6392/23T, 6393/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* 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
CURILEN CAPSULE, HARD 10MG/75MG	CURILEN CAPSULE, HARD 10MG/75MG	6494/20T, 6495/20T, 6496/20T, 6497/20T, 6498/20T, 6499/20T, 6500/20T, 6501/20T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.II.b.1 b) Primary packaging site B.II.b.2 c) 1. Not including batch control/testing B.III.1 b) 4. Deletion of certificates (in case multiple certificates exist per material) B.III.1 b) 3. Updated certificate from an already approved manufacturer B.III.1 b) 2. New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.II.f.1 b) 1. As packaged for sale (supported by real time data) B.II.d.1 a) Tightening of specification limits B.II.b.1 a) Secondary packaging site

CURILEN CAPSULE, HARD 5MG/100MG	CURILEN CAPSULE, HARD 5MG/100MG	6486/20T, 6487/20T, 6488/20T, 6489/20T, 6490/20T, 6491/20T, 6492/20T, 6493/20T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.II.b.1 b) Primary packaging site B.II.b.2 c) 1. Not including batch control/testing B.III.1 b) 4. Deletion of certificates (in case multiple certificates exist per material) B.III.1 b) 3. Updated certificate from an already approved manufacturer B.III.1 b) 2. New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.II.f.1 b) 1. As packaged for sale (supported by real time data) B.II.d.1 a) Tightening of specification limits B.II.b.1 a) Secondary packaging site
CURILEN CAPSULE, HARD 10MG/100MG	CURILEN CAPSULE, HARD 10MG/100MG	6478/20T, 6479/20T, 6480/20T, 6481/20T, 6482/20T, 6483/20T, 6484/20T, 6485/20T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.II.b.1 b) Primary packaging site B.II.b.2 c) 1. Not including batch control/testing B.III.1 b) 4. Deletion of certificates (in case multiple certificates exist per material) B.III.1 b) 3. Updated certificate from an already approved manufacturer B.III.1 b) 2. New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.II.f.1 b) 1. As packaged for sale (supported by real time data) B.II.d.1 a) Tightening of specification limits B.II.b.1 a) Secondary packaging site
CURILEN CAPSULE, HARD 5MG/75MG	CURILEN CAPSULE, HARD 5MG/75MG	6502/20T, 6503/20T, 6504/20T, 6505/20T, 6506/20T, 6507/20T, 6508/20T, 6509/20T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	B.II.b.1 b) Primary packaging site B.II.b.2 c) 1. Not including batch control/testing B.III.1 b) 4. Deletion of certificates (in case multiple certificates exist per material) B.III.1 b) 3. Updated certificate from an already approved manufacturer B.III.1 b) 2. New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.II.f.1 b) 1. As packaged for sale (supported by real time data) B.II.d.1 a) Tightening of specification limits B.II.b.1 a) Secondary packaging site
AMLORINE TABLET 10MG	AMLORINE TABLET 10MG	9672/22T, 9673/22T, 9674/22T, 9675/22T, 9676/22T, 9677/22T, 9678/22T, 9679/22T, 9680/22T, 9681/22T, 9682/22T	REMEDICA LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for 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 i B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT -

				Control of finished product - Change in B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process test A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermed B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in
AMLORINE TABLET 5MG	AMLORINE TABLET 5MG	9683/22T, 9684/22T, 9685/22T, 9686/22T, 9687/22T, 9688/22T, 9689/22T, 9690/22T, 9691/22T, 9692/22T, 9693/22T	REMEDICA LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for 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 i B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process test A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermed B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in
MIDAZOLAM ACCORD SOLUTION FOR INJECTION OR INFUSION 1MG/ML	MIDAZOLAM ACCORD SOLUTION FOR INJECTION OR INFUSION 1MG/ML	6596/23T	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
MIDAZOLAM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	MIDAZOLAM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	6597/23T	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
LASIX TABLET 40MG	LASIX TABLET 40MG	5158/21T	SANOFI WINTHROP INDUSTRIE.	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
SEVOFLURANE-PIRAMAL INHALATION VAPOUR, LIQUID 100% V/V	SEVOFLURANE-PIRAMAL INHALATION VAPOUR, LIQUID 100% V/V	3367/23T	PIRAMAL CRITICAL CARE B.V.	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
ZOVIRAX ORAL SUSPENSION 200MG/5ML	ZOVIRAX ORAL SUSPENSION 200MG/5ML	7319/23T	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.
IMODIUM PLUS TABLET 2MG/125MG	IMODIUM PLUS TABLET 2MG/125MG	5396/23T, 5397/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.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
VEDFA TABLET, FILM COATED 50MG/1000MG	VEDFA TABLET, FILM COATED 50MG/1000MG	5855/22T	PHARMATHEN S.A.	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
VEDFA TABLET, FILM COATED 50MG/850MG	VEDFA TABLET, FILM COATED 50MG/850MG	5856/22T	PHARMATHEN S.A.	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
RIVAROXABAN/SANDOZ TABLET, FILM COATED 20MG	RIVAROXABAN/SANDOZ TABLET, FILM COATED 20MG	3900/23T, 3901/23T, 3902/23T, 3903/23T, 3904/23T	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) 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.a B.II.d.1.a - QUALITY

				CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
RIVAROXABAN/SANDOZ TABLET, FILM COATED 15MG	RIVAROXABAN/SANDOZ TABLET, FILM COATED 15MG	3905/23T, 3906/23T, 3907/23T, 3908/23T, 3909/23T	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) 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.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
RIVAROXABAN/SANDOZ TABLET, FILM COATED 10MG	RIVAROXABAN/SANDOZ TABLET, FILM COATED 10MG	3910/23T, 3911/23T, 3912/23T, 3913/23T, 3914/23T	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) 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.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
SOOLANTRA CREAM 10MG/G	SOOLANTRA CREAM 10MG/G	6700/23T, 6701/23T	GALDERMA INTERNATIONAL,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 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
AREMED TABLET, FILM COATED 1MG	AREMED TABLET, FILM COATED 1MG	7398/23T	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
SYNTOCIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 1000MG	SYNTOCIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 1000MG	7458/23T, 7459/23T, 7460/23T, 7461/23T, 7462/23T, 7463/23T, 7464/23T, 7465/23T, 7466/23T	CODAL SYNTO 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 manufacturi B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specificatio 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 /
SYNTOCIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	SYNTOCIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	7467/23T, 7468/23T, 7469/23T, 7470/23T, 7471/23T, 7472/23T, 7473/23T, 7474/23T, 7475/23T	CODAL SYNTO 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 manufacturi B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specificatio 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 /

SYNTOCIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG	SYNTOCIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG	7476/23T, 7477/23T, 7478/23T, 7479/23T, 7480/23T, 7481/23T, 7482/23T, 7483/23T, 7484/23T	CODAL SYNTO 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 manufacturi B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specificatio 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 /
PRAGIOLA CAPSULE, HARD 300MG	PRAGIOLA CAPSULE, HARD 300MG	935/23T, 939/23T	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
PRAGIOLA CAPSULE, HARD 150MG	PRAGIOLA CAPSULE, HARD 150MG	936/23T, 940/23T	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
PRAGIOLA CAPSULE, HARD 75MG	PRAGIOLA CAPSULE, HARD 75MG	937/23T, 941/23T	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
PRAGIOLA CAPSULE, HARD 25MG	PRAGIOLA CAPSULE, HARD 25MG	938/23T, 942/23T	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
PEROFEN 400 TABLET, FILM COATED 400MG	PEROFEN 400 TABLET, FILM COATED 400MG	7383/23T, 7384/23T	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 corresponding test method
ZILISTEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG	ZILISTEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG	6955/23T	NORIDEM ENTERPRISE S LTD	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	6130/23T	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
TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	6129/23T	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
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	6127/23T	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
TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	6128/23T	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
ACTILYSE POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1MG/ML	ACTILYSE POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 1MG/ML	3470/23T, 3471/23T, 3472/23T, 3473/23T, 3474/23T, 3475/23T, 3476/23T, 3477/23T, 3478/23T, 3479/23T, 3480/23T, 3481/23T, 3482/23T	BOEHRINGER INGELHEIM HELLAS SINGLE MEMBER S.A.	B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in an B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in th B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in th B.II.e.2.z B.II.e.2.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in th

				B.II.e.7.z B.II.e.7.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in su B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process test B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi B.III.2.z B.III.2.z - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with
TUTECVI COMBI TABLET, FILM COATED 50MG/850MG	TUTECVI COMBI TABLET, FILM COATED 50MG/850MG	6056/23T, 6057/23T, 6058/23T, 6059/23T	VIATRIS LIMITED	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.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
TUTECVI COMBI TABLET, FILM COATED 50MG/1000MG	TUTECVI COMBI TABLET, FILM COATED 50MG/1000MG	6052/23T, 6053/23T, 6054/23T, 6055/23T	VIATRIS LIMITED	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process B.II.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
DASATINIB /TEVA TABLET, FILM COATED 20MG	DASATINIB /TEVA TABLET, FILM COATED 20MG	5905/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DASATINIB /TEVA TABLET, FILM COATED 100MG	DASATINIB /TEVA TABLET, FILM COATED 100MG	5902/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DASATINIB /TEVA TABLET, FILM COATED 70MG	DASATINIB /TEVA TABLET, FILM COATED 70MG	5903/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DASATINIB /TEVA TABLET, FILM COATED 50MG	DASATINIB /TEVA TABLET, FILM COATED 50MG	5904/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

PROGRAF CAPSULE, HARD 5MG	PROGRAF CAPSULE, HARD 5MG	5894/23T	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)*
PROGRAF CAPSULE, HARD 1MG	PROGRAF CAPSULE, HARD 1MG	5893/23T	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)*
PROGRAF CAPSULE, HARD 0.5MG	PROGRAF CAPSULE, HARD 0.5MG	5895/23T	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)*
RIVAROLTO TABLET, FILM COATED 15MG	RIVAROLTO TABLET, FILM COATED 15MG	2539/22T, 2540/22T	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
RIVAROLTO TABLET, FILM COATED 2.5MG	RIVAROLTO TABLET, FILM COATED 2.5MG	2543/22T, 2544/22T	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
RIVAROLTO TABLET, FILM COATED 20MG	RIVAROLTO TABLET, FILM COATED 20MG	2541/22T, 2542/22T	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

RIVAROLTO TABLET, FILM COATED 10MG	RIVAROLTO TABLET, FILM COATED 10MG	2537/22T, 2538/22T	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
BIVELEN TABLET, FILM COATED 5MG	BIVELEN TABLET, FILM COATED 5MG	7566/23T	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
BIVELEN TABLET, FILM COATED 7.5MG	BIVELEN TABLET, FILM COATED 7.5MG	7565/23T	DELORBIS PHARMACEUTICALS LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
PROSPAN COUGH SYRUP 7MG/ML	PROSPAN COUGH SYRUP 7MG/ML	7069/23T, 7070/23T	ENGELHARD ARZNEIMITTEL GMBH & CO. KG	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF 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
FAMOPSIN TABLET, FILM COATED 20MG	FAMOPSIN TABLET, FILM COATED 20MG	7397/23T	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
FAMOPSIN TABLET, FILM COATED 40MG	FAMOPSIN TABLET, FILM COATED 40MG	7396/23T	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
NETAXAN EYE GEL (3MG/1MG) /ML	NETAXAN EYE GEL (3MG/1MG) /ML	6217/23T	SIFI S.P.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
CISATRACURIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	CISATRACURIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	6654/23T	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
CISATRACURIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	CISATRACURIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	6653/23T	ACCORD HEALTHCARE S.L.U	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
NETAXAN EYE GEL (3MG/1MG) /ML	NETAXAN EYE GEL (3MG/1MG) /ML	2483/23T	SIFI S.P.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
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	5884/23T	ABBVIE PHARMACEUTICALS S.A.	B.II.b.4.f B.II.b.4.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line)
BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	5885/23T	ABBVIE PHARMACEUTICALS S.A.	B.II.b.4.f B.II.b.4.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line)
PARADIS VAGINAL CAPSULE, HARD	PARADIS VAGINAL CAPSULE, HARD	6300/23T	FREZYDERM S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ROSUVASTATIN ACCORD TABLET, FILM	ROSUVASTATIN ACCORD TABLET, FILM	5654/23T	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

COATED 20MG	COATED 20MG			activities for which the manufacturer/importer is responsible do not include batch release
ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	5656/23T	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
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	5655/23T	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
ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 40MG	5653/23T	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
APOTEL MAX SOLUTION FOR INFUSION 1G/100ML	APOTEL MAX SOLUTION FOR INFUSION 1G/100ML	7561/23T, 7562/23T, 7563/23T	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AZACITIDINE/STADA POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	AZACITIDINE/STADA POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	7049/23T	STADA ARZNEIMITTEL AG	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
AZYTER EYE DROPS,	AZYTER EYE DROPS,	5867/23T, 5868/23T	LABORATOIRES THEA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

SOLUTION 15MG/G	SOLUTION 15MG/G			Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
METHYCOBAL TABLET 500MCG	METHYCOBAL TABLET 500MCG	6318/23T	MEDILINK 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
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G	PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G	307/23T, 308/23T	FRESENIUS KABI HELLAS A.E.	B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product B.II.b.z B.II.b.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Other variation
PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	PIPERACILLIN/TAZOBACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	309/23T, 310/23T	FRESENIUS KABI HELLAS A.E.	B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product B.II.b.z B.II.b.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Other variation
NETAXAN EYE DROPS, SOLUTION (3MG/1MG) /ML	NETAXAN EYE DROPS, SOLUTION (3MG/1MG) /ML	6253/23T	SIFI S.P.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
NETAXAN EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (3MG/1MG) /ML	NETAXAN EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (3MG/1MG) /ML	6254/23T	SIFI S.P.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

NETAXAN EYE DROPS, SOLUTION (3MG/1MG) /ML	NETAXAN EYE DROPS, SOLUTION (3MG/1MG) /ML	2324/23T	SIFI S.P.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
NETAXAN EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (3MG/1MG) /ML	NETAXAN EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (3MG/1MG) /ML	2325/23T	SIFI S.P.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
PANMIGRAN TABLET, FILM COATED 250MG/250MG/65MG	PANMIGRAN TABLET, FILM COATED 250MG/250MG/65MG	5970/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DICLAC 75 ID HEXAL TABLET, PROLONGED-RELEASE 75MG	DICLAC 75 ID HEXAL TABLET, PROLONGED-RELEASE 75MG	7375/23T	HEXAL AG	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
BRADIREM TABLET, FILM COATED 7.5MG	BRADIREM TABLET, FILM COATED 7.5MG	5774/23T	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
BRADIREM TABLET, FILM	BRADIREM TABLET, FILM	5775/23T	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

COATED 5MG	COATED 5MG			MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ANAPEN INJECTION 300MCG/0.3ML	ANAPEN INJECTION 300MCG/0.3ML	1539/23T	BIOPROJET PHARMA	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
ANAPEN JUNIOR SOLUTION FOR INJECTION 150MCG/0.3ML	ANAPEN JUNIOR SOLUTION FOR INJECTION 150MCG/0.3ML	1540/23T	BIOPROJET PHARMA	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
LENALIDOMIDE NORAMEDA CAPSULE, HARD 25MG	LENALIDOMIDE NORAMEDA CAPSULE, HARD 25MG	4844/23T, 4845/23T	UAB NORAMEDA	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
LENALIDOMIDE NORAMEDA CAPSULE, HARD 5MG	LENALIDOMIDE NORAMEDA CAPSULE, HARD 5MG	4850/23T, 4851/23T	UAB NORAMEDA	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
LENALIDOMIDE NORAMEDA CAPSULE, HARD 15MG	LENALIDOMIDE NORAMEDA CAPSULE, HARD 15MG	4846/23T, 4847/23T	UAB NORAMEDA	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY

				CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
LENALIDOMIDE NORAMEDA CAPSULE, HARD 10MG	LENALIDOMIDE NORAMEDA CAPSULE, HARD 10MG	4848/23T, 4849/23T	UAB NORAMEDA	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing
OXIS TURBUHALER POWDER FOR INHALATION 4.5MCG/DOSE	OXIS TURBUHALER POWDER FOR INHALATION 4.5MCG/DOSE	7373/23T, 7374/23T	ASTRAZENECA AB	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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)
OXIS TURBUHALER POWDER FOR INHALATION 9MCG/DOSE	OXIS TURBUHALER POWDER FOR INHALATION 9MCG/DOSE	7371/23T, 7372/23T	ASTRAZENECA AB	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release A.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)

DIAZEM TABLET 60MG	DIAZEM TABLET 60MG	7095/23T	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
REPRAT GAST TABLET, GASTRO-RESISTANT 20MG	REPRAT GAST TABLET, GASTRO-RESISTANT 20MG	7457/23T	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, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
FESOTERODINE ACCORD TABLET, PROLONGED-RELEASE 8MG	FESOTERODINE ACCORD TABLET, PROLONGED-RELEASE 8MG	5231/23T	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
FESOTERODINE ACCORD TABLET, PROLONGED-RELEASE 4MG	FESOTERODINE ACCORD TABLET, PROLONGED-RELEASE 4MG	5228/23T	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
GLIZOREM TABLET 80MG	GLIZOREM TABLET 80MG	1085/23T, 1086/23T, 1087/23T, 1088/23T	REMEDICA LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.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
PANTOPRAZOLE DELORBIS TABLET, GASTRO-RESISTANT 40MG	PANTOPRAZOLE DELORBIS TABLET, GASTRO-RESISTANT 40MG	7497/23T, 7498/23T, 7499/23T	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PIRFENIDONE MSN TABLET, FILM COATED 267MG	PIRFENIDONE MSN TABLET, FILM COATED 267MG	6391/23T	MSN LABS EUROPE 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
PIRFENIDONE MSN TABLET, FILM COATED 801MG	PIRFENIDONE MSN TABLET, FILM COATED 801MG	6390/23T	MSN LABS EUROPE 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
EVECET TABLET, PROLONGED-RELEASE 3MG	EVECET TABLET, PROLONGED-RELEASE 3MG	5034/23T	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

EVECET TABLET, PROLONGED-RELEASE 8MG	EVECET TABLET, PROLONGED-RELEASE 8MG	5032/23T	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
EVECET TABLET, PROLONGED-RELEASE 4MG	EVECET TABLET, PROLONGED-RELEASE 4MG	5033/23T	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
EVECET TABLET, PROLONGED-RELEASE 2MG	EVECET TABLET, PROLONGED-RELEASE 2MG	5035/23T	PHARMATHEN S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
REPRAT TABLET, GASTRO-RESISTANT 40MG	REPRAT TABLET, GASTRO-RESISTANT 40MG	7449/23T	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
REPRAT TABLET, GASTRO-RESISTANT 20MG	REPRAT TABLET, GASTRO-RESISTANT 20MG	7450/23T	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

TIVEL TABLET 1MG	TIVEL TABLET 1MG	7368/23T	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)*
NIFELAT LA TABLET, PROLONGED-RELEASE 60MG	NIFELAT LA TABLET, PROLONGED-RELEASE 60MG	6585/23T	REMEDICA 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)
NIFELAT LA TABLET, PROLONGED-RELEASE 30MG	NIFELAT LA TABLET, PROLONGED-RELEASE 30MG	6586/23T	REMEDICA 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)
OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	6912/23T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
BORTEZOMIB/STADA SOLUTION FOR INJECTION 2.5MG/ML	BORTEZOMIB/STADA SOLUTION FOR INJECTION 2.5MG/ML	5826/23T	STADA ARZNEIMITTEL AG	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
LEVOTHYROXINE ACCORD TABLET 50MCG	LEVOTHYROXINE ACCORD TABLET 50MCG	8401/22T	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
LEVOTHYROXINE ACCORD TABLET 100MCG	LEVOTHYROXINE ACCORD TABLET 100MCG	8400/22T	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
LEVOTHYROXINE ACCORD	LEVOTHYROXINE ACCORD	8402/22T	ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

TABLET 25MCG	TABLET 25MCG			MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 SR SUSTAINED RELEASE TABLETS 75MG	VOLTAREN SR SUSTAINED RELEASE TABLETS 75MG	4744/23T, 4745/23T, 4746/23T	NOVARTIS IRELAND LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.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 -
VOLTAREN SR SUSTAINED RELEASE TABLETS 75MG	VOLTAREN SR SUSTAINED RELEASE TABLETS 75MG	4744/23T, 4745/23T, 4746/23T	NOVARTIS IRELAND LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.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 -
VOLTAREN TABLET, GASTRO-RESISTANT 50MG	VOLTAREN TABLET, GASTRO-RESISTANT 50MG	4738/23T, 4739/23T, 4740/23T	NOVARTIS IRELAND LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.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 -
VOLTAREN TABLET, GASTRO-RESISTANT 50MG	VOLTAREN TABLET, GASTRO-RESISTANT 50MG	4738/23T, 4739/23T, 4740/23T	NOVARTIS IRELAND LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.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 -
VOLTAREN RETARD SUSTAINED RELEASE TABLETS 100MG	VOLTAREN RETARD SUSTAINED RELEASE TABLETS 100MG	4741/23T, 4742/23T, 4743/23T	NOVARTIS IRELAND LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.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 -
VOLTAREN RETARD SUSTAINED RELEASE TABLETS 100MG	VOLTAREN RETARD SUSTAINED RELEASE TABLETS 100MG	4741/23T, 4742/23T, 4743/23T	NOVARTIS IRELAND LIMITED	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.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 -
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	6015/23T	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
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	6017/23T	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
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	6016/23T	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
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	6018/23T	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
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	5240/22T	SANOFI PASTEUR.	C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*
DAKTARIN CREAM 2% W/W	DAKTARIN CREAM 2% W/W	3388/23T, 3389/23T, 3390/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.e.5.d B.II.e.5.d - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products 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.
DEPAKINE CHRONO TABLET, PROLONGED-RELEASE 500MG	DEPAKINE CHRONO TABLET, PROLONGED-RELEASE 500MG	4644/22T	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
AMOXAPEN CAPSULE, HARD 250MG	AMOXAPEN CAPSULE, HARD 250MG	7772/22T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
AMOXAPEN CAPSULE,	AMOXAPEN CAPSULE,	7771/22T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

HARD 500MG	HARD 500MG			MEDICINAL PRODUCTS - Other variation
PACLITAXEL HOSPIRA CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXEL HOSPIRA CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	4136/23T	PFIZER HELLAS AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
REPRATGAST TABLET, GASTRO-RESISTANT 20MG	REPRATGAST TABLET, GASTRO-RESISTANT 20MG	7431/23T, 7432/23T, 7433/23T	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.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)
AMLODIPIN ACCORD TABLET 10MG	AMLODIPIN ACCORD TABLET 10MG	6832/23T	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
AMLODIPIN ACCORD TABLET 5MG	AMLODIPIN ACCORD TABLET 5MG	6833/23T	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
LINEZOLID ACCORD TABLET, FILM COATED 600MG	LINEZOLID ACCORD TABLET, FILM COATED 600MG	6195/23T, 6196/23T	ACCORD HEALTHCARE S.L.U	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.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
TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	6117/23T, 6118/23T	ACCORD HEALTHCARE S.L.U	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.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
TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	TOPIRAMATE ACCORD TABLET, FILM COATED 25MG	6117/23T, 6118/23T	ACCORD HEALTHCARE S.L.U	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.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
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	6111/23T, 6112/23T	ACCORD HEALTHCARE S.L.U	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.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
TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	TOPIRAMATE ACCORD TABLET, FILM COATED 200MG	6111/23T, 6112/23T	ACCORD HEALTHCARE S.L.U	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.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
TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	6113/23T, 6114/23T	ACCORD HEALTHCARE S.L.U	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.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
TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	TOPIRAMATE ACCORD TABLET, FILM COATED 100MG	6113/23T, 6114/23T	ACCORD HEALTHCARE S.L.U	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.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
TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	6115/23T, 6116/23T	ACCORD HEALTHCARE S.L.U	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.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
TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	TOPIRAMATE ACCORD TABLET, FILM COATED 50MG	6115/23T, 6116/23T	ACCORD HEALTHCARE S.L.U	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.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
DENEX TABLET 100MG	DENEX TABLET 100MG	5809/23T	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
ALOPRON TABLET 100MG	ALOPRON TABLET 100MG	5834/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ALOPRON TABLET 300MG	ALOPRON TABLET 300MG	5833/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MOLAXOLE POWDER FOR ORAL SOLUTION	MOLAXOLE POWDER FOR ORAL SOLUTION	6938/23T	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
CAMPTO CONCENT RATE FOR SOLUTION FOR INFUSION 20MG/ML	CAMPTO CONCENT RATE FOR SOLUTION FOR INFUSION 20MG/ML	5059/23T	PFIZER HELLAS AE	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
COSOPT OPHTHAL MIC EYE DROPS, SOLUTION	COSOPT OPHTHAL MIC EYE DROPS, SOLUTION	7307/23T, 7308/23T, 7309/23T	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)* 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 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
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	7434/23T	SAPIENS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
FLEXBUMIN SOLUTION FOR INFUSION 200G/L	FLEXBUMIN SOLUTION FOR INFUSION 200G/L	2640/23T, 2641/23T, 2642/23T, 2643/23T	BAXALTA INNOVATIONS 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 B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
FLEXBUMIN SOLUTION FOR INFUSION 250G/L	FLEXBUMIN SOLUTION FOR INFUSION 250G/L	2636/23T, 2637/23T, 2638/23T, 2639/23T	BAXALTA INNOVATIONS 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 B.I.a.3.e B.I.a.3.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/imm B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the

				manufacturing proc A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting
ULTIMAX ALTER TABLET, FILM COATED 200MG	ULTIMAX ALTER TABLET, FILM COATED 200MG	9664/21T	MEDOCHEMIE LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ULTIMAX ALTER TABLET, FILM COATED 200MG	ULTIMAX ALTER TABLET, FILM COATED 200MG	9664/21T	MEDOCHEMIE LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ULTIMAX ALTER TABLET, FILM COATED 400MG	ULTIMAX ALTER TABLET, FILM COATED 400MG	9665/21T	MEDOCHEMIE LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ULTIMAX ALTER TABLET, FILM COATED 400MG	ULTIMAX ALTER TABLET, FILM COATED 400MG	9665/21T	MEDOCHEMIE LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ADAGREL TABLET, FILM COATED 75MG	ADAGREL TABLET, FILM COATED 75MG	5441/23T	SAPIENS PHARMACEUTICALS LTD	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1ML	2588/23T	ABBVIE PHARMACEUTICALS S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS	2591/23T	ABBVIE PHARMACEUTICALS S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	BOTOX POWDER FOR SOLUTION FOR INJECTION 100 UNITS	2590/23T	ABBVIE PHARMACEUTICALS S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan -

				Other obligations and conditions (e.g. agreed wording + QRD template)
BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	2589/23T	ABBVIE PHARMACEUTICALS S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
FULVESTRANT ACCORD SOLUTION FOR INJECTION IN PREFILLED SYRINGE 250MG/5ML	FULVESTRANT ACCORD SOLUTION FOR INJECTION IN PREFILLED SYRINGE 250MG/5ML	6655/23T	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
VELTIFER ORAL SOLUTION 100MG/5ML	VELTIFER ORAL SOLUTION 100MG/5ML	5761/23T, 5762/23T	RAFARM S.A.	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 C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 400MG/VIAL	TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 400MG/VIAL	4402/22T	DEMO 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
TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 200MG/VIAL	TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 200MG/VIAL	4403/22T	DEMO 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

NEVIRAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	NEVIRAPINE ACCORD TABLET, PROLONGED-RELEASE 400MG	6988/23T	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
SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	SPIRONOLACTONE ACCORD TABLET, FILM COATED 25MG	6281/23T, 6282/23T	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 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)
SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	SPIRONOLACTONE ACCORD TABLET, FILM COATED 100MG	6279/23T, 6280/23T	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 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)
MUCOFALK ORANGE GRANULES FOR ORAL SUSPENSION 3.25G/5G SACHET	MUCOFALK ORANGE GRANULES FOR ORAL SUSPENSION 3.25G/5G SACHET	1442/23T	DR. FALK PHARMA GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority.
TRAZODONE MC TABLET 150MG	TRAZODONE MC TABLET 150MG	6449/23T	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
TRAZODONE MC TABLET 100MG	TRAZODONE MC TABLET 100MG	6450/23T	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
TRAZODONE MC TABLET 50MG	TRAZODONE MC TABLET 50MG	6451/23T	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
PANTOFLUX TABLET, GASTRO-RESISTANT 40MG	PANTOFLUX TABLET, GASTRO-RESISTANT 40MG	6891/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PANTOFLUX TABLET, GASTRO-RESISTANT 20MG	PANTOFLUX TABLET, GASTRO-RESISTANT 20MG	6892/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	3535/23T	CSL BEHRING GMBH	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	3534/23T	CSL BEHRING GMBH	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	3534/23T	CSL BEHRING GMBH	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
BERINERT 500	BERINERT 500	3531/23T	CSL BEHRING GMBH	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation

POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU			resulting from other regulatory procedures - Other variation
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	3531/23T	CSL BEHRING GMBH	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	3533/23T	CSL BEHRING GMBH	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	3533/23T	CSL BEHRING GMBH	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	3536/23T	CSL BEHRING GMBH	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	3532/23T	CSL BEHRING GMBH	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	3532/23T	CSL BEHRING GMBH	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation

ROZOR TABLET, FILM COATED 20MG/10MG	ROZOR TABLET, FILM COATED 20MG/10MG	4262/23T, 4263/23T, 4264/23T, 4265/23T	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
ROZOR TABLET, FILM COATED 10MG/10MG	ROZOR TABLET, FILM COATED 10MG/10MG	4266/23T, 4267/23T, 4268/23T, 4269/23T	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
TOLTERANA PROLONGED RELEASE CAPSULES 2MG	TOLTERANA PROLONGED RELEASE CAPSULES 2MG	6652/23T	PHARMATHEN S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TOLTERANA PROLONGED RELEASE CAPSULES 4MG	TOLTERANA PROLONGED RELEASE CAPSULES 4MG	6651/23T	PHARMATHEN S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ROZOR TABLET, FILM COATED 20MG/10MG	ROZOR TABLET, FILM COATED 20MG/10MG	5563/23T, 5564/23T, 5565/23T, 5566/23T, 5567/23T, 5568/23T, 5569/23T	VIATRIS HEALTHCARE LIMITED.	B.I.d.1.b.1 B.I.d.1.b.1 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance w B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.I.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.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 i A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o

ROZOR TABLET, FILM COATED 10MG/10MG	ROZOR TABLET, FILM COATED 10MG/10MG	5570/23T, 5571/23T, 5572/23T, 5573/23T, 5574/23T, 5575/23T, 5576/23T	VIATRIS HEALTHCARE LIMITED.	B.I.d.1.b.1 B.I.d.1.b.1 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance w B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.I.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.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 i A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o
SOLMUCOL SYRUP 20MG/ML	SOLMUCOL SYRUP 20MG/ML	7230/23T, 7231/23T, 7232/23T	IBSA FARMACEUTICI ITALIA SRL	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+250)MCG/DOSE	ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+250)MCG/DOSE	4845/22T, 4846/22T, 4847/22T, 4848/22T	ELPEN PHARMACEUTICAL CO INC	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of

				the active substance - Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+500)MCG/DOSE	ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+500)MCG/DOSE	4841/22T, 4842/22T, 4843/22T, 4844/22T	ELPEN PHARMACEUTICAL CO INC	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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
ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+100)MCG/DOSE	ROLENIUM INHALATION POWDER, PRE-DISPENSED (50+100)MCG/DOSE	4849/22T, 4850/22T, 4851/22T, 4852/22T	ELPEN PHARMACEUTICAL CO INC	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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
BRUFEDOL TABLET, FILM COATED 600MG	BRUFEDOL TABLET, FILM COATED 600MG	5708/23T, 5709/23T	VIATRIS HEALTHCARE LIMITED.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BRUFEDOL TABLET, FILM COATED 400MG	BRUFEDOL TABLET, FILM COATED 400MG	5710/23T, 5711/23T	VIATRIS HEALTHCARE LIMITED.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
BRUFEDOL TABLET, FILM COATED 200MG	BRUFEDOL TABLET, FILM COATED 200MG	5706/23T, 5707/23T	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
TEMELOR SOLUTION FOR INJECTION 4MG/ML	TEMELOR SOLUTION FOR INJECTION 4MG/ML	9134/22T, 9135/22T	MEDOCHEMIE LTD	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) C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by th C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s)
SUGAMMADEX/PHARMAZAC SOLUTION FOR INJECTION 100 MG/ML	SUGAMMADEX/PHARMAZAC SOLUTION FOR INJECTION 100 MG/ML	5075/23T, 5076/23T, 5077/23T, 5078/23T, 5079/23T, 5080/23T	PHARMAZAC S.A.	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product 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 produc 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 B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f B.II.b.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 proces 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
LEVOXA TABLET, FILM COATED 500MG	LEVOXA TABLET, FILM COATED 500MG	6061/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GAVISCON DOUBLE ACTION ORAL SUSPENSION	GAVISCON DOUBLE ACTION ORAL SUSPENSION	5506/23T	RECKITT BENCKISER HELLAS HEALTHCARE SA	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
NUROFEN DURANCE MEDICATED PLASTER 200MG	NUROFEN DURANCE MEDICATED PLASTER 200MG	5505/23T	RECKITT BENCKISER HELLAS HEALTHCARE SA	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
NUROFEN EXPRESS CAPSULE, SOFT 400MG	NUROFEN EXPRESS CAPSULE, SOFT 400MG	5504/23T	RECKITT BENCKISER HELLAS HEALTHCARE SA	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
MELOX TABLET 7.5MG	MELOX TABLET 7.5MG	4787/23T	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

MELOX TABLET 15MG	MELOX TABLET 15MG	4786/23T	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
THELMOX TABLET, CHEWABLE 100MG	THELMOX TABLET, CHEWABLE 100MG	4669/23T	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
AMIODARONE TABLET 200MG	AMIODARONE TABLET 200MG	7190/23T	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
NAIREM TABLET, FILM COATED 5MG	NAIREM TABLET, FILM COATED 5MG	8676/21T	DEMO S.A.	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings
NAIREM TABLET, FILM COATED 10MG	NAIREM TABLET, FILM COATED 10MG	8677/21T	DEMO S.A.	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings
NAIREM TABLET, FILM COATED 20MG	NAIREM TABLET, FILM COATED 20MG	8678/21T	DEMO S.A.	B.II.a.1.a B.II.a.1.a - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings
PROCARDIN TABLET, FILM COATED 75MG	PROCARDIN TABLET, FILM COATED 75MG	4670/23T	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
MELOX TABLET 7.5MG	MELOX TABLET 7.5MG	4508/23T	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)*
MELOX TABLET 15MG	MELOX TABLET 15MG	4507/23T	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)*
OXYNORM CAPSULE, HARD 10MG	OXYNORM CAPSULE, HARD 10MG	7156/23T	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	OXYNORM CAPSULE, HARD 5MG	7157/23T	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	OXYNORM CAPSULE, HARD 20MG	7155/23T	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
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (2G/0.25G)/ VIAL	PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (2G/0.25G)/ VIAL	5929/23T, 5930/23T	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
PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (4G/0.5G)/VIAL	PIPERACILLIN + TAZOBACTAM/GENERICS POWDER FOR SOLUTION FOR INJECTION /INFUSION (4G/0.5G)/VIAL	5927/23T, 5928/23T	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

CLONOTRIL TABLET 0.5MG	CLONOTRIL TABLET 0.5MG	3615/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CLONOTRIL TABLET 2MG	CLONOTRIL TABLET 2MG	3614/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
COSTI TABLET 10MG	COSTI TABLET 10MG	3964/23T	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
PRIBEKINET SOLUTION FOR INJECTION 5MG/ML	PRIBEKINET SOLUTION FOR INJECTION 5MG/ML	6092/23T	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)
BETALOCZOK TABLET, PROLONGED-RELEASE 25MG	BETALOCZOK TABLET, PROLONGED-RELEASE 25MG	3999/23T, 4000/23T	RECORDATI IRELAND LTD	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release 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)
BETALOCZOK TABLET, PROLONGED-RELEASE 100MG	BETALOCZOK TABLET, PROLONGED-RELEASE 100MG	3995/23T, 3996/23T	RECORDATI IRELAND LTD	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release 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)
BETALOC ZOK TABLET, PROLONG ED-RELEASE 50MG	BETALOC ZOK TABLET, PROLONG ED-RELEASE 50MG	3997/23T, 3998/23T	RECORDATI IRELAND LTD	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release 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)
BETALOC ZOK TABLET, PROLONG ED-RELEASE 200MG	BETALOC ZOK TABLET, PROLONG ED-RELEASE 200MG	3993/23T, 3994/23T	RECORDATI IRELAND LTD	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release 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)
FESOTERO DINE ACCORD TABLET, PROLONG ED-RELEASE 8MG	FESOTERO DINE ACCORD TABLET, PROLONG ED-RELEASE 8MG	6283/23T	ACCORD HEALTHCARE S.L.U	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
SUNITINIB PHARMAS CIENCE CAPSULE, HARD 50MG	SUNITINIB PHARMAS CIENCE CAPSULE, HARD 50MG	5977/23T, 5978/23T, 5979/23T	PHARMASCIE NCE INTERNATION AL LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation B.I.z B.I.z - Quality change - Active substance - Other variation 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 -
SUNITINIB PHARMASCIENCE CAPSULE, HARD 37.5MG	SUNITINIB PHARMASCIENCE CAPSULE, HARD 37.5MG	5980/23T, 5981/23T, 5982/23T	PHARMASCIENCE INTERNATIONAL LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation B.I.z B.I.z - Quality change - Active substance - Other variation 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 -
SUNITINIB PHARMASCIENCE CAPSULE, HARD 25MG	SUNITINIB PHARMASCIENCE CAPSULE, HARD 25MG	5983/23T, 5984/23T, 5985/23T	PHARMASCIENCE INTERNATIONAL LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation B.I.z B.I.z - Quality change - Active substance - Other variation 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 -
SUNITINIB PHARMASCIENCE CAPSULE, HARD 12.5MG	SUNITINIB PHARMASCIENCE CAPSULE, HARD 12.5MG	5986/23T, 5987/23T, 5988/23T	PHARMASCIENCE INTERNATIONAL LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation B.I.z B.I.z - Quality change - Active substance - Other variation 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 -
DELIPOST TABLET, FILM COATED 20MG	DELIPOST TABLET, FILM COATED 20MG	3950/23T	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
DELIPOST TABLET, FILM COATED 40MG	DELIPOST TABLET, FILM COATED 40MG	3949/23T	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

DELIPOST TABLET, FILM COATED 10MG	DELIPOST TABLET, FILM COATED 10MG	3951/23T	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
MODULAIR TABLET, CHEWABLE 5MG	MODULAIR TABLET, CHEWABLE 5MG	3926/23T	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
MODULAIR TABLET, CHEWABLE 4MG	MODULAIR TABLET, CHEWABLE 4MG	3927/23T	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
MODULAIR TABLET, FILM COATED 10MG	MODULAIR TABLET, FILM COATED 10MG	3925/23T	ELPEN PHARMACEUTICAL CO INC	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
AMOXAPEN CAPSULE, HARD 250MG	AMOXAPEN CAPSULE, HARD 250MG	1565/23T	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
AMOXAPEN TABLET, DISPERSIBLE 250MG	AMOXAPEN TABLET, DISPERSIBLE 250MG	1559/23T	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
AMOXAPEN TABLET, FILM	AMOXAPEN TABLET, FILM	1564/23T	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)

COATED 250MG	COATED 250MG			in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMOXAPEN CAPSULE, HARD 500MG	AMOXAPEN CAPSULE, HARD 500MG	1566/23T	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
AMOXAPEN TABLET, FILM COATED 500MG	AMOXAPEN TABLET, FILM COATED 500MG	1563/23T	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
EDAMOX CAPSULE, HARD 500MG	EDAMOX CAPSULE, HARD 500MG	1560/23T	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
AMOXAPEN POWDER FOR ORAL SUSPENSION 125MG/5ML	AMOXAPEN POWDER FOR ORAL SUSPENSION 125MG/5ML	1561/23T	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
AMOXAPEN POWDER FOR ORAL SUSPENSI	AMOXAPEN POWDER FOR ORAL SUSPENSI	1562/23T	REMEDICA LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)

ON 250MG/5ML	ON 250MG/5ML			in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
YENLIP PESSARY 100MG	YENLIP PESSARY 100MG	6538/23T	VERISFIELD SINGLE MEMBER S.A.	B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing
PROMETHAZINE TABLET, FILM COATED 25MG	PROMETHAZINE TABLET, FILM COATED 25MG	7297/23T, 7298/23T	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.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
PROMETHAZINE TABLET, FILM COATED 10MG	PROMETHAZINE TABLET, FILM COATED 10MG	7299/23T, 7300/23T	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.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
BETAISODONA VAGINAL SUPPOSITORIES 200MG	BETAISODONA VAGINAL SUPPOSITORIES 200MG	2865/23T, 2866/23T, 2867/23T, 2868/23T, 2869/23T, 2870/23T	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

				B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.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
VILDAGLIPTIN PHARMATHEN TABLET 50MG	VILDAGLIPTIN PHARMATHEN TABLET 50MG	6126/23T	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
MEDOPRAZOLE GASTRO-RESISTANT CAPSULE, HARD 20MG	MEDOPRAZOLE GASTRO-RESISTANT CAPSULE, HARD 20MG	6445/23T	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
TIENAM POWDER FOR SOLUTION FOR INFUSION (500MG/500MG)VIAL	TIENAM POWDER FOR SOLUTION FOR INFUSION (500MG/500MG)VIAL	837/23T, 838/23T, 839/23T, 840/23T, 841/23T	MERCK SHARP & DOHME BV	B.II.d.1.e B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved sp B.II.d.1.b B.II.d.1.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification li B.II.d.1.f B.II.d.1.f - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a specification pa B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specificatio B.II.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
LAMOSYNT TABLET 200MG	LAMOSYNT TABLET 200MG	6900/23T, 6901/23T, 6902/23T	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 - 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)*
LAMOSYNT TABLET 50MG	LAMOSYNT TABLET 50MG	6906/23T, 6907/23T, 6908/23T	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 - 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)*
LAMOSYNT TABLET 25MG	LAMOSYNT TABLET 25MG	6909/23T, 6910/23T, 6911/23T	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 - 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)*
LAMOSYNT TABLET 100MG	LAMOSYNT TABLET 100MG	6903/23T, 6904/23T, 6905/23T	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 - 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)*
BREXIN TABLET 20MG	BREXIN TABLET 20MG	6858/23T, 6859/23T, 6860/23T, 6861/23T, 6862/23T, 6863/23T	CHIESI HELLAS 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 bat B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addit 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
BINOSTO EFFERVES CENT TABLET 70MG	BINOSTO EFFERVES CENT TABLET 70MG	6332/23T	GALENICA SA	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location
CLOPIDOG REL ACCORD TABLET, FILM COATED 75MG	CLOPIDOG REL ACCORD TABLET, FILM COATED 75MG	6656/23T	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
TIENAM POWDER FOR SOLUTION FOR INFUSION (500MG/50 0MG)VIAL	TIENAM POWDER FOR SOLUTION FOR INFUSION (500MG/50 0MG)VIAL	829/23T, 830/23T, 831/23T, 832/23T, 833/23T, 834/23T, 835/23T, 836/23T	MERCK SHARP & DOHME BV	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substanc 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 - 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 th B.I.b.1.e B.I.b.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finis B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ
TIENAM POWDER FOR SOLUTION FOR INFUSION (500MG/50 0MG)VIAL	TIENAM POWDER FOR SOLUTION FOR INFUSION (500MG/50 0MG)VIAL	829/23T, 830/23T, 831/23T, 832/23T, 833/23T, 834/23T, 835/23T, 836/23T	MERCK SHARP & DOHME BV	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substanc 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 -

				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 th B.I.b.1.e B.I.b.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finis B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, includ
CLOMIPRAMINE TABLET, FILM COATED 25MG	CLOMIPRAMINE TABLET, FILM COATED 25MG	6839/23T, 6840/23T	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 corresponding test method
AFEKSIN SOLUBLE TABLET 20MG	AFEKSIN SOLUBLE TABLET 20MG	6237/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 2MG	AMARYL TABLET 2MG	4761/23T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 3MG	AMARYL TABLET 3MG	4760/23T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 1MG	AMARYL TABLET 1MG	4762/23T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
AMARYL TABLET 4MG	AMARYL TABLET 4MG	4759/23T	SANOFI WINTHROP INDUSTRIE.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
BICALUTAMIDE/RAFARM TABLET, FILM COATED 50MG	BICALUTAMIDE/RAFARM TABLET, FILM COATED 50MG	4389/23T	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
BICALUTAMIDE/RAFARM TABLET, FILM COATED 150MG	BICALUTAMIDE/RAFARM TABLET, FILM COATED 150MG	4388/23T	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
REGAINE CUTANEOUS SOLUTION 5% W/V	REGAINE CUTANEOUS SOLUTION 5% W/V	6187/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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
CODAXOL SOLUTION FOR INJECTION OR INFUSION 0.4MG/ML	CODAXOL SOLUTION FOR INJECTION OR INFUSION 0.4MG/ML	7296/23T	CODAL-SYNTO 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)
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 125MCG/5MCG	FLUTIFORM PRESSURISED INHALATION, SUSPENSION 125MCG/5MCG	6189/23T	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 50MCG/5MCG	FLUTIFORM PRESSURISED INHALATION, SUSPENSION 50MCG/5MCG	6190/23T	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLUTIFORM PRESSURISED INHALATION, SUSPENSION 250MCG/10MCG	FLUTIFORM PRESSURISED INHALATION, SUSPENSION 250MCG/10MCG	6188/23T	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PARACETAMOL SAPIENS SOLUTION FOR	PARACETAMOL SAPIENS SOLUTION FOR	6725/23T	SAPIENS PHARMACEUTICALS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package

INFUSION 10MG/ML	INFUSION 10MG/ML			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
ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	7623/22T, 7624/22T, 7625/22T, 7626/22T, 7627/22T, 7628/22T, 7629/22T	SANDOZ GMBH	A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.I.a.2.e B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes B.I.a.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
ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	5181/21T, 5182/21T	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
ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	2860/21T	SANDOZ GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	500/22T, 501/22T, 502/22T, 503/22T, 504/22T	SANDOZ GMBH	B.I.d.1.z B.I.d.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Other variation 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
ERLOTINIB SANDOZ	ERLOTINIB SANDOZ	941/21T, 942/21T, 943/21T	SANDOZ GMBH	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE -

TABLET, FILM COATED 150MG	TABLET, FILM COATED 150MG			Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.I.a.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
ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	10174/20T	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GEFITINIB SANDOZ TABLET, FILM COATED 250MG	GEFITINIB SANDOZ TABLET, FILM COATED 250MG	10173/20T	SANDOZ GMBH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LORIVAN TABLET 1MG	LORIVAN TABLET 1MG	7182/23T	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
LORIVAN TABLET 2MG	LORIVAN TABLET 2MG	7181/23T	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
BETNOVATE CREAM 0.1% W/W	BETNOVATE CREAM 0.1% W/W	5942/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
BLOONIS TABLET, FILM COATED 5MG	BLOONIS TABLET, FILM COATED 5MG	3762/23T, 3763/23T, 3764/23T	ZENTIVA K.S.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - 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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NOLVADEX -D TABLET, FILM COATED 20MG	NOLVADEX -D TABLET, FILM COATED 20MG	7165/23T	ASTRAZENEC A 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
NOLVADEX TABLET, FILM COATED 10MG	NOLVADEX TABLET, FILM COATED 10MG	7166/23T	ASTRAZENEC A 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
ETOPOSID E ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 20MG/ML	ETOPOSID E ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 20MG/ML	6232/22T	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)*
ZOVAR TABLET, FILM COATED 10MG	ZOVAR TABLET, FILM COATED 10MG	7236/23T	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

ZOVAR TABLET, FILM COATED 40MG	ZOVAR TABLET, FILM COATED 40MG	7234/23T	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
ZOVAR TABLET, FILM COATED 80MG	ZOVAR TABLET, FILM COATED 80MG	7233/23T	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
ZOVAR TABLET, FILM COATED 20MG	ZOVAR TABLET, FILM COATED 20MG	7235/23T	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
MYDOFLEX TABLET, FILM COATED 150MG	MYDOFLEX TABLET, FILM COATED 150MG	7286/23T	M K STAVRINOS LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template
TRACRIUM INJECTION 10MG/ML	TRACRIUM INJECTION 10MG/ML	7161/23T, 7162/23T	ASPEN PHARMA TRADING 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) 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 -
PALEXIA ORAL SOLUTION 20MG/ML	PALEXIA ORAL SOLUTION 20MG/ML	6559/23T, 6560/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or

				limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
PALEXIA RETARD TABLET, PROLONGED-RELEASE 50MG	PALEXIA RETARD TABLET, PROLONGED-RELEASE 50MG	6557/23T, 6558/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
PALEXIA TABLET, FILM COATED 75MG	PALEXIA TABLET, FILM COATED 75MG	6563/23T, 6564/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
PALEXIA TABLET, FILM COATED 50MG	PALEXIA TABLET, FILM COATED 50MG	6565/23T, 6566/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting

				material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
PALEXIA RETARD TABLET, PROLONGED-RELEASE 25MG	PALEXIA RETARD TABLET, PROLONGED-RELEASE 25MG	6547/23T, 6548/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
PALEXIA RETARD TABLET, PROLONGED-RELEASE 200MG	PALEXIA RETARD TABLET, PROLONGED-RELEASE 200MG	6551/23T, 6552/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
PALEXIA RETARD TABLET, PROLONGED-	PALEXIA RETARD TABLET, PROLONGED-	6549/23T, 6550/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in

RELEASE 250MG	RELEASE 250MG			the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
PALEXIA TABLET, FILM COATED 100MG	PALEXIA TABLET, FILM COATED 100MG	6567/23T, 6568/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
PALEXIA RETARD TABLET, PROLONGED-RELEASE 100MG	PALEXIA RETARD TABLET, PROLONGED-RELEASE 100MG	6555/23T, 6556/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
PALEXIA ORAL SOLUTION 4MG/ML	PALEXIA ORAL SOLUTION 4MG/ML	6561/23T, 6562/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active

				substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
PALEXIA RETARD TABLET, PROLONGED-RELEASE 150MG	PALEXIA RETARD TABLET, PROLONGED-RELEASE 150MG	6553/23T, 6554/23T	GRUNENTHAL GMBH	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.a.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
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	5068/20T	ACCORD HEALTHCARE S.L.U	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	5067/20T	ACCORD HEALTHCARE S.L.U	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TIENAM POWDER FOR SOLUTION FOR INFUSION (500MG/500MG)VIAL	TIENAM POWDER FOR SOLUTION FOR INFUSION (500MG/500MG)VIAL	4796/23T	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
ATORVASTATIN ACCORD TABLET, FILM	ATORVASTATIN ACCORD TABLET, FILM	5672/23T	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

COATED 10MG	COATED 10MG			quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
ATORVASTATIN ACCORD TABLET, FILM COATED 20MG	ATORVASTATIN ACCORD TABLET, FILM COATED 20MG	5671/23T	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
ATORVASTATIN ACCORD TABLET, FILM COATED 40MG	ATORVASTATIN ACCORD TABLET, FILM COATED 40MG	5670/23T	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
LEFLON TABLET, FILM COATED 10MG	LEFLON TABLET, FILM COATED 10MG	6041/23T, 6042/23T, 6043/23T, 6044/23T, 6045/23T, 6046/23T, 6047/23T	PHARMATHEN S.A.	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LEFLON TABLET, FILM COATED 20MG	LEFLON TABLET, FILM COATED 20MG	6034/23T, 6035/23T, 6036/23T, 6037/23T, 6038/23T, 6039/23T, 6040/23T	PHARMATHEN S.A.	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LEFLON TABLET, FILM COATED 100MG	LEFLON TABLET, FILM COATED 100MG	6027/23T, 6028/23T, 6029/23T, 6030/23T, 6031/23T, 6032/23T, 6033/23T	PHARMATHEN S.A.	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LEFLON TABLET, FILM COATED 15MG	LEFLON TABLET, FILM COATED 15MG	6020/23T, 6021/23T, 6022/23T, 6023/23T, 6024/23T, 6025/23T, 6026/23T	PHARMATHEN S.A.	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	6122/23T	BAXALTA INNOVATIONS GMBH	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	6120/23T	BAXALTA INNOVATIONS GMBH	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance

HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 200G/L	6121/23T	BAXALTA INNOVATIONS GMBH	B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
DIAZEPAM ACCORD TABLET 10MG	DIAZEPAM ACCORD TABLET 10MG	6337/23T, 6338/23T, 6339/23T, 6340/23T	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
DIAZEPAM ACCORD TABLET 5MG	DIAZEPAM ACCORD TABLET 5MG	6341/23T, 6342/23T, 6343/23T, 6344/23T	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
ALENDRONIC ACID ACCORD TABLET 70MG	ALENDRONIC ACID ACCORD TABLET 70MG	5669/23T	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
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 500IU	5816/23T, 5817/23T	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 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
BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	5814/23T, 5815/23T	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 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
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	5791/21T	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

MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	5792/21T	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
MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	MYFORTIC GASTRO-RESISTANT COATED TABLETS 180MG	1734/22T	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	MYFORTIC GASTRO-RESISTANT COATED TABLETS 360MG	1735/22T	NOVARTIS IRELAND LIMITED	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
BICOL TABLET, FILM COATED 6.25MG	BICOL TABLET, FILM COATED 6.25MG	7127/23T, 7128/23T, 7129/23T, 7130/23T	DELORBIS PHARMACEUTICALS LTD	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 - Downscalin B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an app B.II.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

BICOL TABLET, FILM COATED 12.5MG	BICOL TABLET, FILM COATED 12.5MG	7123/23T, 7124/23T, 7125/23T, 7126/23T	DELORBIS PHARMACEUTICALS LTD	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 - Downscalin B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an app B.II.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
BICOL TABLET, FILM COATED 25MG	BICOL TABLET, FILM COATED 25MG	7119/23T, 7120/23T, 7121/23T, 7122/23T	DELORBIS PHARMACEUTICALS LTD	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 - Downscalin B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-f B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing proces B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an app B.II.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
TAVANIC TABLET, FILM COATED 500MG	TAVANIC TABLET, FILM COATED 500MG	4347/23T, 4348/23T	SANOFI WINTHROP INDUSTRIE.	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period - B.III.1.a.3 B.III.1.a.3 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
REVAMOX TABLET, FILM COATED 200MG	REVAMOX TABLET, FILM COATED 200MG	4360/23T	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
TARONTAL MODIFIED-RELEASE TABLET 400MG	TARONTAL MODIFIED-RELEASE TABLET 400MG	4085/23T	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
LEVOMED TABLET 100MG/25MG	LEVOMED TABLET 100MG/25MG	6976/23T	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
LEVOMED TABLET 100MG/10MG	LEVOMED TABLET 100MG/10MG	6977/23T	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
LEVOMED TABLET 250MG/25MG	LEVOMED TABLET 250MG/25MG	6975/23T	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
MELGESIC TABLET 7.5MG	MELGESIC TABLET 7.5MG	5135/23T	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
MELGESIC TABLET 15MG	MELGESIC TABLET 15MG	5134/23T	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
LEVOXACIN TABLET, FILM COATED 250MG	LEVOXACIN TABLET, FILM COATED 250MG	6209/23T	SAPIENS PHARMACEUTICALS LTD	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
ANASTROZOLE ACCORD TABLET, FILM COATED 1MG	ANASTROZOLE ACCORD TABLET, FILM COATED 1MG	6003/23T, 6004/23T	ACCORD HEALTHCARE S.L.U	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.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
ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	6958/23T	PIRAMAL CRITICAL CARE B.V.	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

ROZOR TABLET, FILM COATED 20MG/10MG	ROZOR TABLET, FILM COATED 20MG/10MG	9873/22T, 9874/22T, 9875/22T, 9876/22T, 9877/22T, 9878/22T	VIATRIS HEALTHCARE LIMITED.	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o B.I.b.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.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 i B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.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,
ROZOR TABLET, FILM COATED 10MG/10MG	ROZOR TABLET, FILM COATED 10MG/10MG	9879/22T, 9880/22T, 9881/22T, 9882/22T, 9883/22T, 9884/22T	VIATRIS HEALTHCARE LIMITED.	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; o B.I.b.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.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 i B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/in B.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,
ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	ZOLEDRONIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	9384/22T	ALTAN PHARMACEUTICALS S.A.	B.II.e.1.b.2 B.II.e.1.b.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/ immunological medicinal products
ULCERAN TABLET,	ULCERAN TABLET,	6322/23T	MEDOCHEMIE LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -

FILM COATED 40MG	FILM COATED 40MG			HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ULCERAN TABLET, FILM COATED 20MG	ULCERAN TABLET, FILM COATED 20MG	6323/23T	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
ULTRAVIST 370 SOLUTION FOR INJECTION 76.9%	ULTRAVIST 370 SOLUTION FOR INJECTION 76.9%	1376/23T, 1377/23T	BAYER HELLAS ABEE	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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 300 SOLUTION FOR INJECTION 62.34%	ULTRAVIST 300 SOLUTION FOR INJECTION 62.34%	1378/23T, 1379/23T	BAYER HELLAS ABEE	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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

SEPTOBORE EYE DROPS	SEPTOBORE EYE DROPS	6124/23T, 6125/23T	COOPER PHARMACEUTICALS SA (COOPER S.A.)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Implementation of QRD template 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
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 40MG	PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 40MG	6269/23T	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
PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 20MG	PANTOPRAZOLE AUROBINDO TABLET, GASTRO-RESISTANT 20MG	6270/23T	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
ENTEVIREM TABLET, FILM COATED 0.5MG	ENTEVIREM TABLET, FILM COATED 0.5MG	7184/23T	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
ENTEVIREM TABLET, FILM COATED 1MG	ENTEVIREM TABLET, FILM COATED 1MG	7183/23T	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
CLARIPEN GRANULES FOR ORAL SUSPENSION 250MG/5ML	CLARIPEN GRANULES FOR ORAL SUSPENSION 250MG/5ML	7066/23T	ELPEN PHARMACEUTICAL CO INC	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure

NORETHISTERONE TABLET 5MG	NORETHISTERONE TABLET 5MG	7175/23T, 7176/23T, 7177/23T, 7178/23T, 7179/23T, 7180/23T	REMEDICA LTD	B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharm B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monogra B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active su B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / A.7 A.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
ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG	ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG	4423/23T	SANDOZ PHARMACEUTICALS D.D.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 1.5G	ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 1.5G	4424/23T	SANDOZ PHARMACEUTICALS D.D.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
TRIACOR TABLET, PROLONGED-RELEASE 5MG/5MG	TRIACOR TABLET, PROLONGED-RELEASE 5MG/5MG	423/23T	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
ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	5127/23T, 5128/23T, 5129/23T, 5130/23T, 5131/23T	PIRAMAL CRITICAL CARE B.V.	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
ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	4970/23T	PIRAMAL CRITICAL CARE 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)
ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	ISOFLURANE INHALATION VAPOUR, LIQUID 100% V/V	5132/23T	PIRAMAL CRITICAL CARE B.V.	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
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	6882/23T	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)
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	6881/23T	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)
ARESTON TABLET, FILM COATED 50MG	ARESTON TABLET, FILM COATED 50MG	5399/23T	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
TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/10MG	TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/10MG	4079/23T	LES LABORATOIRES SERVIER	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	TRIPLIXAM TABLET, FILM	4078/23T	LES LABORATOIRES SERVIER	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

COATED 5MG/1.25MG/5MG	COATED 5MG/1.25MG/5MG			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 10MG/2.5MG/10MG	TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/10MG	4081/23T	LES LABORATOIRES SERVIER	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 10MG/2.5MG/5MG	TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/5MG	4080/23T	LES LABORATOIRES SERVIER	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)
DAMIRAST TABLET, FILM COATED 500MCG	DAMIRAST TABLET, FILM COATED 500MCG	5873/23T	ELPEN PHARMACEUTICAL CO INC	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)
VERACOLIM POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1G	VERACOLIM POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1G	5556/23T	NORIDEM ENTERPRISES LTD	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
CLINIMIX N14G30E SOLUTION FOR INFUSION	CLINIMIX N14G30E SOLUTION FOR INFUSION	704/22T	BAXTER (HELLAS) EPE	B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue
CLINIMIX N14G30E SOLUTION FOR INFUSION	CLINIMIX N14G30E SOLUTION FOR INFUSION	3392/22T	BAXTER (HELLAS) EPE	B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
CLINIMIX N14G30E SOLUTION FOR INFUSION	CLINIMIX N14G30E SOLUTION FOR INFUSION	5448/23T	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
RANOLAZINE ELC TABLET, PROLONGED-RELEASE 750MG	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 750MG	1511/23T, 1512/23T, 1513/23T, 1514/23T, 1515/23T, 1516/23T	ELC GROUP S.R.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
RANOLAZINE ELC TABLET, PROLONGED-RELEASE 375MG	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 375MG	1523/23T, 1524/23T, 1525/23T, 1526/23T, 1527/23T, 1528/23T	ELC GROUP S.R.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
RANOLAZINE ELC TABLET, PROLONGED-RELEASE 500MG	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 500MG	1517/23T, 1518/23T, 1519/23T, 1520/23T, 1521/23T, 1522/23T	ELC GROUP S.R.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
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 40MG	ROSUVASTATIN AUROBINDO TABLET, FILM COATED 40MG	2837/23T, 2838/23T, 2839/23T	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 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)*
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 5MG	ROSUVASTATIN AUROBINDO TABLET, FILM COATED 5MG	2846/23T, 2847/23T, 2848/23T	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 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)*
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 10MG	ROSUVASTATIN AUROBINDO TABLET, FILM COATED 10MG	2843/23T, 2844/23T, 2845/23T	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

				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)*
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 20MG	ROSUVASTATIN AUROBINDO TABLET, FILM COATED 20MG	2840/23T, 2841/23T, 2842/23T	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 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)*
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 40MG	ROSUVASTATIN AUROBINDO TABLET, FILM COATED 40MG	750/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 5MG	ROSUVASTATIN AUROBINDO TABLET, FILM COATED 5MG	753/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
ROSUVASTATIN AUROBINDO TABLET, FILM COATED 10MG	ROSUVASTATIN AUROBINDO TABLET, FILM COATED 10MG	752/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
ROSUVASTATIN AUROBINDO TABLET, FILM	ROSUVASTATIN AUROBINDO TABLET, FILM	751/23T	AUROBINDO PHARMA (MALTA) LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient

COATED 20MG	COATED 20MG			
MECOLZINE SUPPOSITORY 500MG	MECOLZINE SUPPOSITORY 500MG	9621/21T	FAES FARMA SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MECOLZINE SUPPOSITORY 1000MG	MECOLZINE SUPPOSITORY 1000MG	9622/21T	FAES FARMA SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NIZORAL CREAM 2%	NIZORAL CREAM 2%	2593/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
IMATINIB TAD TABLET, FILM COATED 100MG	IMATINIB TAD TABLET, FILM COATED 100MG	5392/23T	TAD PHARMA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
IMATINIB TAD TABLET, FILM COATED 400MG	IMATINIB TAD TABLET, FILM COATED 400MG	5393/23T	TAD PHARMA GMBH	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NEPHROTECT SOLUTION FOR INFUSION 10%	NEPHROTECT SOLUTION FOR INFUSION 10%	5388/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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
LAMOTRIX TABLET 50MG	LAMOTRIX TABLET 50MG	6747/23T	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
LAMOTRIX TABLET 200MG	LAMOTRIX TABLET 200MG	6745/23T	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
LAMOTRIX TABLET 100MG	LAMOTRIX TABLET 100MG	6746/23T	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
LAMOTRIX TABLET 25MG	LAMOTRIX TABLET 25MG	6748/23T	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
BICOL TABLET, FILM COATED 12.5MG	BICOL TABLET, FILM COATED 12.5MG	7090/23T	DELORBIS PHARMACEUTICALS LTD	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
MOXILEN CAPSULE, HARD 500MG	MOXILEN CAPSULE, HARD 500MG	7096/23T	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
MOXILEN CAPSULE, HARD 250MG	MOXILEN CAPSULE, HARD 250MG	7097/23T	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
BICOL TABLET, FILM COATED 6.25MG	BICOL TABLET, FILM COATED 6.25MG	7083/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size

BICOL TABLET, FILM COATED 25MG	BICOL TABLET, FILM COATED 25MG	7082/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
NUROFEN EXPRESS TABLET 256MG	NUROFEN EXPRESS TABLET 256MG	24/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
STREPSILS STRAWBERRY SUGAR FREE LOZENGE	STREPSILS STRAWBERRY SUGAR FREE LOZENGE	47/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
STREPSILS LEMON SUGAR FREE LOZENGE	STREPSILS LEMON SUGAR FREE LOZENGE	20/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NUROFEN EXPRESS TABLET 512MG	NUROFEN EXPRESS TABLET 512MG	19/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
STREPSILS ORANGE WITH VITAMIN C LOZENGE	STREPSILS ORANGE WITH VITAMIN C LOZENGE	21/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
STREPSILS HONEY & LEMON LOZENGE	STREPSILS HONEY & LEMON LOZENGE	22/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NUROFEN COLD & FLU	NUROFEN COLD & FLU	26/22T	RECKITT BENCKISER HELLAS	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance,

TABLET, FILM COATED	TABLET, FILM COATED		HEALTHCARE SA	intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NUROFEN TABLET, FILM COATED 200MG	NUROFEN TABLET, FILM COATED 200MG	25/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
STREPSILS COOL LOZENGE	STREPSILS COOL LOZENGE	23/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
NUROFEN TABLET, FILM COATED 200MG	NUROFEN TABLET, FILM COATED 200MG	8529/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
LENALIDOMIDE STADA CAPSULE, HARD 7.5MG	LENALIDOMIDE STADA CAPSULE, HARD 7.5MG	5350/23T, 5351/23T, 5352/23T, 5353/23T, 5354/23T, 5355/23T, 5356/23T, 5357/23T, 5358/23T, 5359/23T, 5360/23T, 5361/23T	STADA ARZNEIMITTEL AG	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 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.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
LENALIDOMIDE STADA CAPSULE, HARD 2.5MG	LENALIDOMIDE STADA CAPSULE, HARD 2.5MG	5374/23T, 5375/23T, 5376/23T, 5377/23T, 5378/23T, 5379/23T, 5380/23T, 5381/23T, 5382/23T, 5383/23T, 5384/23T, 5385/23T	STADA ARZNEIMITTEL AG	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 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.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
LENALIDOMIDE STADA CAPSULE, HARD 10MG	LENALIDOMIDE STADA CAPSULE, HARD 10MG	5338/23T, 5339/23T, 5340/23T, 5341/23T, 5342/23T, 5343/23T, 5344/23T, 5345/23T, 5346/23T, 5347/23T, 5348/23T, 5349/23T	STADA ARZNEIMITTEL AG	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 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.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
LENALIDOMIDE STADA CAPSULE, HARD 20MG	LENALIDOMIDE STADA CAPSULE, HARD 20MG	5314/23T, 5315/23T, 5316/23T, 5317/23T, 5318/23T, 5319/23T, 5320/23T, 5321/23T, 5322/23T, 5323/23T, 5324/23T, 5325/23T	STADA ARZNEIMITTEL AG	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 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.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
LENALIDOMIDE STADA CAPSULE, HARD 5MG	LENALIDOMIDE STADA CAPSULE, HARD 5MG	5362/23T, 5363/23T, 5364/23T, 5365/23T, 5366/23T, 5367/23T, 5368/23T, 5369/23T, 5370/23T, 5371/23T, 5372/23T, 5373/23T	STADA ARZNEIMITTEL AG	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 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.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
LENALIDOMIDE STADA CAPSULE, HARD 15MG	LENALIDOMIDE STADA CAPSULE, HARD 15MG	5326/23T, 5327/23T, 5328/23T, 5329/23T, 5330/23T, 5331/23T, 5332/23T, 5333/23T, 5334/23T, 5335/23T, 5336/23T, 5337/23T	STADA ARZNEIMITTEL AG	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 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.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
LENALIDOMIDE STADA CAPSULE, HARD 25MG	LENALIDOMIDE STADA CAPSULE, HARD 25MG	5302/23T, 5303/23T, 5304/23T, 5305/23T, 5306/23T, 5307/23T, 5308/23T, 5309/23T, 5310/23T, 5311/23T, 5312/23T, 5313/23T	STADA ARZNEIMITTEL AG	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 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.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
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML IN PRE-FILLED SYRINGE	PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML IN PRE-FILLED SYRINGE	5222/23T	FRESENIUS KABI 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.
PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML IN PRE-FILLED SYRINGE	PROPOFOL MCT/LCT/FRESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML IN PRE-FILLED SYRINGE	5221/23T	FRESENIUS KABI 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.
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	4973/23T	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	4972/23T	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	4975/23T	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	4974/23T	MUNDIPHARMA PHARMACEUTICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	OCTAGAM SOLUTION FOR INFUSION 50MG/ML	4509/23T, 4510/23T, 4511/23T	OCTAPHARMA (IP) SPRL	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.a.3.c B.I.a.3.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The change requires assessment of the comparability of a biological/immunological active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in 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
BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	5262/23T	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
BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	BERINERT 500 POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/INJECTION 500IU	5263/23T	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
BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	BERINERT 2000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000IU	5261/23T	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
BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU	5260/23T	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
CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	CREON 20000 GASTRO-RESISTANT CAPSULE, HARD 20000U	5847/23T	VIATRIS HEALTHCARE LIMITED.	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer
CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	CREON 35000 GASTRO-RESISTANT CAPSULE, HARD 35000U	5846/23T	VIATRIS HEALTHCARE LIMITED.	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/

				intermediate/or excipient - Updated certificate from an already approved manufacturer
TICOVAC JUNIOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.25ML/DOSE	TICOVAC JUNIOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.25ML/DOSE	5724/23T, 5725/23T	PFIZER HELLAS AE	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
TICOVAC SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.5ML/DOSE	TICOVAC SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 0.5ML/DOSE	5722/23T, 5723/23T	PFIZER HELLAS AE	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
LENALIDOMIDE STADA CAPSULE, HARD 25MG	LENALIDOMIDE STADA CAPSULE, HARD 25MG	5277/23T	STADA ARZNEIMITTEL AG	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
REMEDOL 6+ ORAL SUSPENSION 250MG/5ML	REMEDOL 6+ ORAL SUSPENSION 250MG/5ML	3928/23T, 3929/23T, 3930/23T, 3931/23T, 3932/23T	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/intermedia B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. E B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the
REMEDOL SUPPOSIT	REMEDOL SUPPOSIT	3938/23T, 3939/23T, 3940/23T, 3941/23T, 3942/23T	REMEDICA LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

ORY 125MG	ORY 125MG			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.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. E B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the
REMEDOL SUPPOSITORY 250MG	REMEDOL SUPPOSITORY 250MG	3933/23T, 3934/23T, 3935/23T, 3936/23T, 3937/23T	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/intermedia B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. E B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the
REMEDOL SUPPOSITORY 500MG	REMEDOL SUPPOSITORY 500MG	3943/23T, 3944/23T, 3945/23T, 3946/23T, 3947/23T	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/intermedia B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with

				a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. E B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the
REMEDOL ORAL SUSPENSION 120MG/5ML	REMEDOL ORAL SUSPENSION 120MG/5ML	4104/23T, 4105/23T, 4106/23T, 4107/23T, 4108/23T	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/intermedia B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermedia B.III.2.a.1 B.III.2.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. E B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the
ISOPTO-MAXITROL EYE OINTMENT	ISOPTO-MAXITROL EYE OINTMENT	6937/23T	NOVARTIS IRELAND LIMITED	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 75MG	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 75MG	6562/22T	PHARMATHEN S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED	6565/22T	PHARMATHEN S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)

SYRINGE 150MG	SYRINGE 150MG			
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 100MG AND 150MG	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 100MG AND 150MG	6564/22T	PHARMATHEN S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 25MG	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 25MG	6563/22T	PHARMATHEN S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 50MG	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 50MG	6566/22T	PHARMATHEN S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 100MG	PSOKADRON PROLONGED RELEASE SUSPENSION FOR INJECTION IN PREFILLED SYRINGE 100MG	6561/22T	PHARMATHEN S.A.	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)
SYNTOCLAV TABLET, FILM COATED 625MG	SYNTOCLAV TABLET, FILM COATED 625MG	6378/23T, 6379/23T	CODAL SYNTO LTD	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.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)
SYNTOCLAV TABLET, FILM	SYNTOCLAV TABLET, FILM	6380/23T, 6381/23T	CODAL SYNTO 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

COATED 375MG	COATED 375MG			limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method 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)
REMEDOL TABLET 500MG	REMEDOL TABLET 500MG	6485/23T	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
REMEDOL FC TABLET, FILM COATED 500MG	REMEDOL FC TABLET, FILM COATED 500MG	6486/23T	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
PARACETAMOL-REMEDICA TABLET 500MG	PARACETAMOL-REMEDICA TABLET 500MG	6487/23T	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
GAVISCON DOUBLE ACTION TABLET, CHEWABLE	GAVISCON DOUBLE ACTION TABLET, CHEWABLE	4984/23T	RECKITT BENCKISER HELLAS HEALTHCARE SA	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
GLATIRAMER/MYLAN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG/ML	GLATIRAMER/MYLAN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 40MG/ML	5086/23T	MYLAN IRELAND LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ROPIVACAINE KABI SOLUTION FOR INJECTION 2MG/ML	ROPIVACAINE KABI SOLUTION FOR INJECTION 2MG/ML	5044/23T, 5045/23T	FRESENIUS KABI HELLAS A.E.	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process

				test B.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
ROPIVACAINE KABI SOLUTION FOR INFUSION 2MG/ML	ROPIVACAINE KABI SOLUTION FOR INFUSION 2MG/ML	5042/23T, 5043/23T	FRESENIUS KABI HELLAS A.E.	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.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
ROPIVACAINE KABI SOLUTION FOR INJECTION 5MG/ML	ROPIVACAINE KABI SOLUTION FOR INJECTION 5MG/ML	5040/23T, 5041/23T	FRESENIUS KABI HELLAS A.E.	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.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
ROPIVACAINE KABI SOLUTION FOR INJECTION 7.5MG/ML	ROPIVACAINE KABI SOLUTION FOR INJECTION 7.5MG/ML	5038/23T, 5039/23T	FRESENIUS KABI HELLAS A.E.	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.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
ROPIVACAINE KABI SOLUTION FOR	ROPIVACAINE KABI SOLUTION FOR	5036/23T, 5037/23T	FRESENIUS KABI HELLAS A.E.	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

INJECTION 10MG/ML	INJECTION 10MG/ML			manufacture of the finished product - Deletion of a non-significant in-process test 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
AZITHRAN TABLET, FILM COATED 250MG	AZITHRAN TABLET, FILM COATED 250MG	775/23T, 776/23T	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 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
CHORIOMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	CHORIOMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	4293/23T	IBSA FARMACEUTICI ITALIA SRL	B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination
PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	6401/23T	CODAL-SYNTO LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIAL	6400/23T	CODAL-SYNTO LIMITED	B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - Change that does not affect the product information
LAMOTRIX TABLET 50MG	LAMOTRIX TABLET 50MG	5242/23T, 5243/23T, 5244/23T	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 - 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)*
LAMOTRIX TABLET 25MG	LAMOTRIX TABLET 25MG	5245/23T, 5246/23T, 5247/23T	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 - 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)*
LAMOTRIX TABLET 200MG	LAMOTRIX TABLET 200MG	5236/23T, 5237/23T, 5238/23T	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 - 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)*
LAMOTRIX TABLET 100MG	LAMOTRIX TABLET 100MG	5239/23T, 5240/23T, 5241/23T	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 - 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)*
VACONTIL CAPSULE, HARD 2MG	VACONTIL CAPSULE, HARD 2MG	6225/23T	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
VACONTIL TABLET 2MG	VACONTIL TABLET 2MG	6218/23T	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
DAKTARIN POWDER 2% W/W	DAKTARIN POWDER 2% W/W	5647/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

				Updated certificate from an already approved manufacturer
DAKTARIN POWDER 2% W/W	DAKTARIN POWDER 2% W/W	4542/23T, 4543/23T, 4544/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product A.z A.z - ADMINISTRATIVE CHANGES - Change in the nomenclature of the container material for immediate packaging of the finished product
DAKTODOR CREAM (2% + 1%) w/w	DAKTODOR CREAM (2% + 1%) w/w	5651/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LIDOCAINE HYDROCHLORIDE NORIDEM SOLUTION FOR INJECTION 10 MG/ML	LIDOCAINE HYDROCHLORIDE NORIDEM SOLUTION FOR INJECTION 10 MG/ML	6620/23T	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
LIDOCAINE HYDROCHLORIDE NORIDEM SOLUTION FOR INJECTION 20 MG/ML	LIDOCAINE HYDROCHLORIDE NORIDEM SOLUTION FOR INJECTION 20 MG/ML	6619/23T	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
GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	GAMUNEX 10% SOLUTION FOR INFUSION 100MG/ML	5673/23T, 5674/23T	GRIFOLS DEUTSCHLAND GMBH.	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.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
REPRAT TABLET, GASTRO-RESISTANT 40MG	REPRAT TABLET, GASTRO-RESISTANT 40MG	7050/23T	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, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
REPRAT TABLET, GASTRO-RESISTANT 20MG	REPRAT TABLET, GASTRO-RESISTANT 20MG	7051/23T	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, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
FERROUS GLUCONATE TABLET, FILM COATED 300MG	FERROUS GLUCONATE TABLET, FILM COATED 300MG	6842/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
FERROUS GLUCONATE TABLET, FILM COATED 300MG	FERROUS GLUCONATE TABLET, FILM COATED 300MG	6446/23T	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)*
FRENOLYN POWDER FOR INHALATION 200MCG/DOSE	FRENOLYN POWDER FOR INHALATION 200MCG/DOSE	6277/23T, 6278/23T	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
FRENOLYN POWDER FOR INHALATION 400MCG/DOSE	FRENOLYN POWDER FOR INHALATION 400MCG/DOSE	6275/23T, 6276/23T	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
NIZORAL SHAMPOO 20MG/G	NIZORAL SHAMPOO 20MG/G	4396/23T, 4397/23T, 4398/23T, 4399/23T, 4400/23T	STADA ARZNEIMITTEL AG	B.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other

				changes to a test procedure (including replacement or addition) B.II.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.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Second B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primar B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site w
MUPIDERM OINTMENT 2% W/W	MUPIDERM OINTMENT 2% W/W	6158/23T	KLEVA PHARMACEU TICALS S.A. (TRADING AS KLEVA S.A.)	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
STRIVERDI RESPIMAT SOLUTION FOR INHALATIO N	STRIVERDI RESPIMAT SOLUTION FOR INHALATIO N	4703/23T, 4704/23T, 4705/23T, 4706/23T, 4707/23T	BOEHRINGER INGELHEIM INTERNATION AL GMBH	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other changes B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance B.I.b.1.h B.I.b.1.h - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue
HEXARHIN AL NASAL SPRAY, SOLUTION 1MG/ML	HEXARHIN AL NASAL SPRAY, SOLUTION 1MG/ML	3414/23T, 3415/23T, 3416/23T, 3417/23T, 3418/23T, 3419/23T, 3420/23T, 3421/23T, 3422/23T, 3423/23T, 3424/23T, 3425/23T, 3426/23T, 3427/23T, 3428/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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.4.c B.II.e.4.c - QUALITY CHANGES - FINISHED PRODUCT -

				Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.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
HEXARHINAL NASAL SPRAY, SOLUTION 1MG/ML	HEXARHINAL NASAL SPRAY, SOLUTION 1MG/ML	3550/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	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
BETNOVATE SCALP APPLICATION CUTANEOUS SOLUTION 0.1% W/W	BETNOVATE SCALP APPLICATION CUTANEOUS SOLUTION 0.1% W/W	5938/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
LOSARTAN AUROBINDO TABLET, FILM COATED 50MG	LOSARTAN AUROBINDO TABLET, FILM COATED 50MG	5811/23T	AUROBINDO PHARMA (MALTA) LIMITED	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
PAROXETINE AUROBINDO TABLET, FILM COATED 30MG	PAROXETINE AUROBINDO TABLET, FILM COATED 30MG	5848/23T, 5849/23T	AUROBINDO PHARMA (MALTA) LIMITED	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PAROXETINE AUROBINDO TABLET, FILM COATED 20MG	PAROXETINE AUROBINDO TABLET, FILM COATED 20MG	5850/23T, 5851/23T	AUROBINDO PHARMA (MALTA) LIMITED	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS

				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AZACITIDINE PHARMASCIENCE POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	AZACITIDINE PHARMASCIENCE POWDER FOR SUSPENSION FOR INJECTION 25MG/ML	5699/23T	PHARMASCIENCE INTERNATIONAL LTD	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
SULVORID TABLET 50MG	SULVORID TABLET 50MG	5103/23T	CODAL-SYNTO LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
SULVORID TABLET 100MG	SULVORID TABLET 100MG	5102/23T	CODAL-SYNTO LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
SULVORID TABLET 25MG	SULVORID TABLET 25MG	5104/23T	CODAL-SYNTO LIMITED	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
ISOPTO-MAXITROL EYE DROPS, SUSPENSION	ISOPTO-MAXITROL EYE DROPS, SUSPENSION	6841/23T	NOVARTIS IRELAND LIMITED	B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the

				Ph. Eur. or national pharmacopoeia of a Member State
RIVAROXABAN/SANDOZ TABLET, FILM COATED 10MG	RIVAROXABAN/SANDOZ TABLET, FILM COATED 10MG	3919/23T	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)
REPRAT TABLET, GASTRO-RESISTANT 40MG	REPRAT TABLET, GASTRO-RESISTANT 40MG	6925/23T	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
REPRAT TABLET, GASTRO-RESISTANT 20MG	REPRAT TABLET, GASTRO-RESISTANT 20MG	6926/23T	DELORBIS PHARMACEUTICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition)
MYELOMIDE CAPSULE, HARD 25MG	MYELOMIDE CAPSULE, HARD 25MG	4296/23T	ANABIOSIS PC.	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
MYELOMIDE CAPSULE, HARD 5MG	MYELOMIDE CAPSULE, HARD 5MG	4299/23T	ANABIOSIS PC.	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
MYELOMIDE CAPSULE, HARD 15MG	MYELOMIDE CAPSULE, HARD 15MG	4297/23T	ANABIOSIS PC.	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
MYELOMIDE CAPSULE, HARD 10MG	MYELOMIDE CAPSULE, HARD 10MG	4298/23T	ANABIOSIS PC.	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
DERMOVATE CREAM 0.05% W/W	DERMOVATE CREAM 0.05% W/W	6874/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
SMOFKABIVEN EXTRA NITROGEN EMULSION FOR INFUSION	SMOFKABIVEN EXTRA NITROGEN EMULSION FOR INFUSION	3540/23T, 3541/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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) 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 - To increase the shelf-life in accordance with ICH guidelines and amend storage conditions (e.g. decrease in temperature to preserve longer shelf-life)
SMOFKABIVEN EXTRA NITROGEN ELECTROLYTE FREE EMULSION FOR INFUSION	SMOFKABIVEN EXTRA NITROGEN ELECTROLYTE FREE EMULSION FOR INFUSION	3538/23T, 3539/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	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) 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 - To increase the shelf-life in accordance with ICH guidelines and amend storage conditions (e.g. decrease in temperature to preserve longer shelf-life)
XATRAL SUSTAINED RELEASE TABLETS 5MG	XATRAL SUSTAINED RELEASE TABLETS 5MG	6452/22T, 6453/22T, 6454/22T, 6455/22T, 6456/22T	SANOFI WINTHROP INDUSTRIE.	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 su B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi 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

XATRAL OD TABLET, PROLONGED-RELEASE 10MG	XATRAL OD TABLET, PROLONGED-RELEASE 10MG	6447/22T, 6448/22T, 6449/22T, 6450/22T, 6451/22T	SANOFI WINTHROP INDUSTRIE.	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 su B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturi 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
PARCOTEN COLD & FLU TABLET, FILM COATED 500MG/30MG/15MG/60MG	PARCOTEN COLD & FLU TABLET, FILM COATED 500MG/30MG/15MG/60MG	5899/23T	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
MELOREM TABLET 15MG	MELOREM TABLET 15MG	6109/23T	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
MELOREM TABLET 7.5MG	MELOREM TABLET 7.5MG	6110/23T	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
MOXICLAV TABLET, FILM COATED 1G	MOXICLAV TABLET, FILM COATED 1G	6735/23T	MEDOCHEMIE LTD	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
CEFUROXIME-SYNTO TABLET, FILM COATED 250MG	CEFUROXIME-SYNTO TABLET, FILM COATED 250MG	6853/23T	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
CEFUROXIME-SYNTO TABLET, FILM COATED 500MG	CEFUROXIME-SYNTO TABLET, FILM COATED 500MG	6852/23T	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
CEFUROXIME-SYNTO TABLET, FILM COATED 250MG	CEFUROXIME-SYNTO TABLET, FILM COATED 250MG	4981/23T, 4982/23T	CODAL-SYNTO LIMITED	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
CEFUROXIME-SYNTO TABLET, FILM COATED 500MG	CEFUROXIME-SYNTO TABLET, FILM COATED 500MG	4979/23T, 4980/23T	CODAL-SYNTO LIMITED	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
NAROX TABLET, FILM COATED 90MG	NAROX TABLET, FILM COATED 90MG	6679/23T, 6680/23T, 6681/23T, 6682/23T, 6683/23T, 6684/23T, 6685/23T	DELORBIS PHARMACEUTICALS 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 A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.b.1.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
NAROX TABLET, FILM COATED 30MG	NAROX TABLET, FILM COATED 30MG	6693/23T, 6694/23T, 6695/23T, 6696/23T, 6697/23T, 6698/23T, 6699/23T	DELORBIS PHARMACEUTICALS 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 A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.b.1.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
NAROX TABLET, FILM COATED 60MG	NAROX TABLET, FILM COATED 60MG	6686/23T, 6687/23T, 6688/23T, 6689/23T, 6690/23T, 6691/23T, 6692/23T	DELORBIS PHARMACEUTICALS 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 A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.b.1.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
NAROX TABLET, FILM COATED 120MG	NAROX TABLET, FILM COATED 120MG	6672/23T, 6673/23T, 6674/23T, 6675/23T, 6676/23T, 6677/23T, 6678/23T	DELORBIS PHARMACEUTICALS 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 A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the

				active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss B.I.b.1.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
NEURONTIN CAPSULE, HARD 400MG	NEURONTIN CAPSULE, HARD 400MG	5869/23T, 5870/23T	UPJOHN HELLAS LTD	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) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
NEURONTIN CAPSULE, HARD 300MG	NEURONTIN CAPSULE, HARD 300MG	5871/23T, 5872/23T	UPJOHN HELLAS LTD	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) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CREON 10000 CAPSULE, HARD 150MG	CREON 10000 CAPSULE, HARD 150MG	6819/23T	VIATRIS HEALTHCARE LIMITED.	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For

				an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer
XYZAL ORAL SOLUTION 0.5MG/ML	XYZAL ORAL SOLUTION 0.5MG/ML	1776/23T	UCB PHARMA SA	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
AMESOL TABLET, FILM COATED 250MG	AMESOL TABLET, FILM COATED 250MG	6662/23T	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
AMESOL TABLET, FILM COATED 500MG	AMESOL TABLET, FILM COATED 500MG	6661/23T	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
ZADITEN EYE DROPS, SOLUTION 0.25MG/ML	ZADITEN EYE DROPS, SOLUTION 0.25MG/ML	5168/23T	LABORATOIRES THEA	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
OCULOTECT FLUID SINE EYE DROPS 5G/100ML	OCULOTECT FLUID SINE EYE DROPS 5G/100ML	5167/23T	LABORATOIRES THEA	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
VOLTAREN OPHTHA	VOLTAREN OPHTHA	5166/23T	LABORATOIRES THEA	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name

EYE DROPS 0.1%	EYE DROPS 0.1%			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
CALCIUM LACTATE TABLET 300MG	CALCIUM LACTATE TABLET 300MG	4930/23T	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
ROSUVASTATIN/MYLAN TABLET, FILM COATED 10MG	ROSUVASTATIN/MYLAN TABLET, FILM COATED 10MG	5891/23T	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSUVASTATIN/MYLAN TABLET, FILM COATED 20MG	ROSUVASTATIN/MYLAN TABLET, FILM COATED 20MG	5890/23T	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSUVASTATIN/MYLAN TABLET, FILM COATED 5MG	ROSUVASTATIN/MYLAN TABLET, FILM COATED 5MG	5892/23T	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ROSUVASTATIN/MYLAN TABLET, FILM COATED 40MG	ROSUVASTATIN/MYLAN TABLET, FILM COATED 40MG	5889/23T	MYLAN IRELAND LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
TRIPLIXAM TABLET, FILM COATED	TRIPLIXAM TABLET, FILM COATED	4096/23T	LES LABORATOIRES SERVIER	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 -

5MG/1.25MG/10MG	5MG/1.25MG/10MG			Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/10MG	TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/10MG	4098/23T	LES LABORATOIRES SERVIER	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
TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/5MG	TRIPLIXAM TABLET, FILM COATED 10MG/2.5MG/5MG	4097/23T	LES LABORATOIRES SERVIER	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
TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/5MG	TRIPLIXAM TABLET, FILM COATED 5MG/1.25MG/5MG	4095/23T	LES LABORATOIRES SERVIER	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
LOMEXIN VAGINAL CAPSULE, SOFT 200MG	LOMEXIN VAGINAL CAPSULE, SOFT 200MG	3374/22T	RECORDATI IRELAND LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LOMEXIN VAGINAL CAPSULE, SOFT 600MG	LOMEXIN VAGINAL CAPSULE, SOFT 600MG	3375/22T	RECORDATI IRELAND LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CARBOPLATIN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	CARBOPLATIN ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	2444/23T	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
MUNDISAL GEL ORAL GEL 8.71% W/W	MUNDISAL GEL ORAL GEL 8.71% W/W	4817/22T, 4818/22T, 4819/22T, 4820/22T, 4821/22T, 4822/22T, 4823/22T, 4824/22T, 4825/22T, 4826/22T, 4827/22T, 4828/22T	MUNDIPHARMA PHARMACEUTICALS LTD	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 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, 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.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 - B.I.a.3.b B.I.a.3.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used i B.I.a.1.z B.I.a.1.z - Addition of an alternative site for manufacture and/or storage of the AS (if it's not part of the same pharmaceutical group). If the site is alr
AUDAX EAR DROPS 20% W/V	AUDAX EAR DROPS 20% W/V	4829/22T, 4830/22T, 4831/22T, 4832/22T, 4833/22T, 4834/22T, 4835/22T, 4836/22T, 4837/22T, 4838/22T, 4839/22T, 4840/22T	MUNDIPHARMA PHARMACEUTICALS LTD	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 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, 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.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 - B.I.a.3.b B.I.a.3.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used i B.I.a.1.z B.I.a.1.z - Addition of an alternative site for manufacture and/or storage of the AS (if it's not part of the same pharmaceutical group). If the site is alr
TENOVIRAL TABLET, FILM COATED 123MG	TENOVIRAL TABLET, FILM COATED 123MG	4478/23T	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)
TENOVIRAL TABLET, FILM COATED 163MG	TENOVIRAL TABLET, FILM COATED 163MG	4477/23T	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)
TENOVIRAL TABLET, FILM	TENOVIRAL TABLET, FILM	4475/23T	REMEDICA LTD	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

COATED 245MG	COATED 245MG			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)
TENOVIRAL TABLET, FILM COATED 204MG	TENOVIRAL TABLET, FILM COATED 204MG	4476/23T	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)
ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 10MG	4460/23T, 4461/23T	ACCORD HEALTHCARE S.L.U	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.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	ROSUVASTATIN ACCORD TABLET, FILM COATED 20MG	4458/23T, 4459/23T	ACCORD HEALTHCARE S.L.U	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.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 5MG	ROSUVASTATIN ACCORD TABLET, FILM COATED 5MG	4462/23T, 4463/23T	ACCORD HEALTHCARE S.L.U	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.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	ROSUVASTATIN ACCORD TABLET, FILM	4456/23T, 4457/23T	ACCORD HEALTHCARE S.L.U	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 -

COATED 40MG	COATED 40MG			Minor changes to an approved test procedure 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
XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	5407/23T, 5408/23T	MERZ PHARMACEUTICALS GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	5405/23T, 5406/23T	MERZ PHARMACEUTICALS GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
XEOMIN POWDER FOR SOLUTION FOR INJECTION 200 UNITS	XEOMIN POWDER FOR SOLUTION FOR INJECTION 200 UNITS	5403/23T, 5404/23T	MERZ PHARMACEUTICALS GMBH	B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
NALION TABLET 0.5MG	NALION TABLET 0.5MG	3300/23T	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
NALION TABLET 0.25MG	NALION TABLET 0.25MG	3301/23T	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
NOVOFEN TABLET 20MG	NOVOFEN TABLET 20MG	3312/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NOVOFEN TABLET 10MG	NOVOFEN TABLET 10MG	3313/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

VILLAMOS OD TABLET, ORODISPE RSIBLE 20MG	VILLAMOS OD TABLET, ORODISPE RSIBLE 20MG	4355/23T	ELPEN PHARMACEU TICAL CO INC	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
VILLAMOS OD TABLET, ORODISPE RSIBLE 5MG	VILLAMOS OD TABLET, ORODISPE RSIBLE 5MG	4358/23T	ELPEN PHARMACEU TICAL CO INC	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
VILLAMOS OD TABLET, ORODISPE RSIBLE 15MG	VILLAMOS OD TABLET, ORODISPE RSIBLE 15MG	4356/23T	ELPEN PHARMACEU TICAL CO INC	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
VILLAMOS OD TABLET, ORODISPE RSIBLE 10MG	VILLAMOS OD TABLET, ORODISPE RSIBLE 10MG	4357/23T	ELPEN PHARMACEU TICAL CO INC	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
SEREVENT DISKUS POWDER FOR INHALATIO N 50MCG	SEREVENT DISKUS POWDER FOR INHALATIO N 50MCG	5940/23T	GLAXOSMITH KLINE (IRELAND) LIMITED	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FUGENTIN POWDER FOR ORAL SUSPENSI ON 1G	FUGENTIN POWDER FOR ORAL SUSPENSI ON 1G	887/23T, 888/23T	ELPEN PHARMACEU TICAL 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
SYNTOCINON CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTION 10 IU/ML	SYNTOCINON CONCENTRATE FOR SOLUTION FOR INFUSION AND INJECTION 10 IU/ML	6669/23T	VIATRIS HEALTHCARE LIMITED.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
NAROX TABLET, FILM COATED 30MG	NAROX TABLET, FILM COATED 30MG	6788/23T	DELORBIS PHARMACEUTICALS LTD	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
NAROX TABLET, FILM COATED 90MG	NAROX TABLET, FILM COATED 90MG	6786/23T	DELORBIS PHARMACEUTICALS LTD	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
NAROX TABLET, FILM COATED 120MG	NAROX TABLET, FILM COATED 120MG	6785/23T	DELORBIS PHARMACEUTICALS LTD	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
NAROX TABLET, FILM COATED 60MG	NAROX TABLET, FILM COATED 60MG	6787/23T	DELORBIS PHARMACEUTICALS LTD	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
MEDOSTATIN TABLET 20MG	MEDOSTATIN TABLET 20MG	3082/23T	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
MEDOSTATIN TABLET 40MG	MEDOSTATIN TABLET 40MG	3081/23T	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
VIDELMET TABLET, FILM COATED 50MG/1000MG	VIDELMET TABLET, FILM COATED 50MG/1000MG	6789/23T	DELORBIS PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release

VIDELMET TABLET, FILM COATED 50MG/850MG	VIDELMET TABLET, FILM COATED 50MG/850MG	6790/23T	DELORBIS PHARMACEUTICALS LTD	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
MONOREM TABLET 20MG	MONOREM TABLET 20MG	6477/23T, 6478/23T, 6479/23T, 6480/23T	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/intermedia B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a B.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.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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
MONOREM R TABLET, PROLONGED-RELEASE 60MG	MONOREM R TABLET, PROLONGED-RELEASE 60MG	6481/23T, 6482/23T, 6483/23T, 6484/23T	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/intermedia B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a B.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.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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
NYSTALOCAL CREAM (100000U.I/1MG/11.5MG)/G	NYSTALOCAL CREAM (100000U.I/1MG/11.5MG)/G	2900/23T, 2901/23T	A.D.L. PHARMACEUTICAL PRODUCTSLINE LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For

				an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 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
AMLODIPIN ACCORD TABLET 10MG	AMLODIPIN ACCORD TABLET 10MG	5751/23T	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
AMLODIPIN ACCORD TABLET 5MG	AMLODIPIN ACCORD TABLET 5MG	5752/23T	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
LAMISIL TABLET 250MG	LAMISIL TABLET 250MG	1940/21T	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
LAMISIL TABLET 250MG	LAMISIL TABLET 250MG	1940/21T	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
LAMISIL TABLET 125MG	LAMISIL TABLET 125MG	1939/21T	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
LAMISIL TABLET 125MG	LAMISIL TABLET 125MG	1939/21T	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
AUGMENTIN ES POWDER	AUGMENTIN ES POWDER	2093/23T, 2094/23T	GLAXOSMITHKLINE	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

FOR ORAL SUSPENSION (600+42.9) MG/5ML	FOR ORAL SUSPENSION (600+42.9) MG/5ML		(IRELAND) LIMITED	Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in 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.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
PANTOPRAZOLE ACCORD POWDER FOR SOLUTION FOR INJECTION 40MG/VIAL	PANTOPRAZOLE ACCORD POWDER FOR SOLUTION FOR INJECTION 40MG/VIAL	8025/21T	ACCORD HEALTHCARE S.L.U	B.II.b.1.d B.II.b.1.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site which requires an initial or product specific inspection
DEXETA EYE DROPS, SOLUTION 1.5MG/ML	DEXETA EYE DROPS, SOLUTION 1.5MG/ML	2477/23T	SIFI S.P.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
DEXETA EYE DROPS, SOLUTION 1.5MG/ML	DEXETA EYE DROPS, SOLUTION 1.5MG/ML	1509/23T, 1510/23T	SIFI S.P.A	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Increase of the batch size up to 10-fold for the pharmaceutical form medicinal gas 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
SYNTOCLAV TABLET, FILM COATED 875/125MG	SYNTOCLAV TABLET, FILM COATED 875/125MG	6363/23T, 6364/23T	CODAL-SYNTO LIMITED	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.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	ERLOTINIB REMEDICA TABLET, FILM COATED 25MG	6107/23T	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
ERLOTINIB REMEDICA TABLET, FILM COATED 100MG	ERLOTINIB REMEDICA TABLET, FILM COATED 100MG	6106/23T	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
ERLOTINIB REMEDICA TABLET, FILM COATED 150MG	ERLOTINIB REMEDICA TABLET, FILM COATED 150MG	6105/23T	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
ERLOTINIB REMEDICA TABLET, FILM COATED 50MG	ERLOTINIB REMEDICA TABLET, FILM COATED 50MG	6108/23T	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
PENRAZOL GASTRO-RESISTANT CAPSULE, HARD 20MG	PENRAZOL GASTRO-RESISTANT CAPSULE, HARD 20MG	2949/23T, 2950/23T	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 C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)

				in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
LANSO GASTRO-RESISTANT CAPSULE, HARD 30MG	LANSO GASTRO-RESISTANT CAPSULE, HARD 30MG	6284/23T, 6285/23T	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.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 -
PONSTAN FORTE TABLET, FILM COATED 500MG	PONSTAN FORTE TABLET, FILM COATED 500MG	3195/22T	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
XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS	5402/23T	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
XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	XEOMIN POWDER FOR SOLUTION FOR INJECTION 100 UNITS	5401/23T	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
XEOMIN POWDER FOR SOLUTION FOR INJECTION 200 UNITS	XEOMIN POWDER FOR SOLUTION FOR INJECTION 200 UNITS	5400/23T	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
AKILEN TABLET, FILM COATED 80MG	AKILEN TABLET, FILM COATED 80MG	6326/23T, 6327/23T	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
AKILEN TABLET, FILM COATED 40MG	AKILEN TABLET, FILM COATED 40MG	6328/23T, 6329/23T	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
JIVOLAR TABLET, FILM COATED 50MG/850MG	JIVOLAR TABLET, FILM COATED 50MG/850MG	4241/23T	MEDOCHEMIE LTD	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
JIVOLAR TABLET, FILM COATED 50MG/1000MG	JIVOLAR TABLET, FILM COATED 50MG/1000MG	4240/23T	MEDOCHEMIE LTD	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
AMPICILLIN/SULBACTAM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G/1G	AMPICILLIN/SULBACTAM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G/1G	3294/23T	APTA MEDICA INTERNACIONAL D.O.O.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
AMPICILLIN/SULBACTAM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/0.5G	AMPICILLIN/SULBACTAM APTAPHARMA POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/0.5G	3295/23T	APTA MEDICA INTERNACIONAL D.O.O.	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ERMYCIN TABLET, FILM COATED 500MG	ERMYCIN TABLET, FILM COATED 500MG	6230/23T, 6231/23T, 6232/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes A.3 A.3 - ADMINISTRATIVE CHANGES

				- Change in name of the active substance or of an excipient
ERMYCIN TABLET, FILM COATED 250MG	ERMYCIN TABLET, FILM COATED 250MG	6227/23T, 6228/23T, 6229/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
ATALINE SYRUP 1.5MG/5ML	ATALINE SYRUP 1.5MG/5ML	6320/23T	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)*
ADRENALINE INJECTION 1MG/ML	ADRENALINE INJECTION 1MG/ML	6411/23T	NORIDEM ENTERPRISES 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)*
MONTOL TABLET, CHEWABLE 4MG	MONTOL TABLET, CHEWABLE 4MG	5820/23T	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
MONTOL TABLET, CHEWABLE 5MG	MONTOL TABLET, CHEWABLE 5MG	5819/23T	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
MONTOL TABLET, FILM COATED 10MG	MONTOL TABLET, FILM COATED 10MG	5818/23T	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
OCTISET VAGINAL SOLUTION	OCTISET VAGINAL SOLUTION	6093/23T, 6094/23T, 6095/23T	T.C.CHRISTOFOROU LTD.	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
OCTISET CUTANEOUS SOLUTION	OCTISET CUTANEOUS SOLUTION	6096/23T, 6097/23T, 6098/23T	T.C.CHRISTOFOROU LTD.	B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.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
MYOVIEW KIT FOR RADIOPHARMACEUTICAL PREPARATION 0.23MG	MYOVIEW KIT FOR RADIOPHARMACEUTICAL PREPARATION 0.23MG	4422/22T, 4423/22T	GE HEALTHCARE AS (NYDALEN)	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GEODON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 20MG/ML	GEODON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 20MG/ML	4302/23T	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GEODON CAPSULE, HARD 60MG	GEODON CAPSULE, HARD 60MG	4304/23T	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GEODON CAPSULE, HARD 80MG	GEODON CAPSULE, HARD 80MG	4303/23T	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
EPANUTIN CAPSULE, HARD 100MG	EPANUTIN CAPSULE, HARD 100MG	4307/23T	VIATRIS HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CARDURA TABLET 2MG	CARDURA TABLET 2MG	4301/23T	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name

				and/or address of the marketing authorisation holder
CARDURA TABLET 4MG	CARDURA TABLET 4MG	4300/23T	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GEODON CAPSULE, HARD 40MG	GEODON CAPSULE, HARD 40MG	4305/23T	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
GEODON CAPSULE, HARD 20MG	GEODON CAPSULE, HARD 20MG	4306/23T	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CASPOFUNGIN SAPIENS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 70MG	CASPOFUNGIN SAPIENS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 70MG	9029/22T, 9030/22T	SAPIENS PHARMACEUTICALS LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
CASPOFUNGIN SAPIENS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 50MG	CASPOFUNGIN SAPIENS POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 50MG	9031/22T, 9032/22T	SAPIENS PHARMACEUTICALS LTD	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF
NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	602/23T, 603/23T	BIAL-PORTELA & CA, SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NOPRILAM 250 POWDER FOR ORAL SUSPENSION (250MG/62.5MG)/5ML	NOPRILAM 250 POWDER FOR ORAL SUSPENSION (250MG/62.5MG)/5ML	600/23T, 601/23T	BIAL-PORTELA & CA, SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NOPRILAM 500 TABLET, FILM COATED	NOPRILAM 500 TABLET, FILM COATED	606/23T, 607/23T	BIAL-PORTELA & CA, SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

(500MG/125MG)	(500MG/125MG)			
NOPRILAMDT TABLET, FILM COATED 1000MG	NOPRILAMDT TABLET, FILM COATED 1000MG	604/23T, 605/23T	BIAL-PORTELA & CA, SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NOPRILAMDT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	NOPRILAMDT POWDER FOR ORAL SUSPENSION (400MG/57MG)/5ML	608/23T, 609/23T	BIAL-PORTELA & CA, SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SENNA TABLET 7.5MG	SENNA TABLET 7.5MG	4710/23T	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
GLYFORMIN TABLET, FILM COATED 850MG	GLYFORMIN TABLET, FILM COATED 850MG	5611/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
GLYFORMIN TABLET, FILM COATED 500MG	GLYFORMIN TABLET, FILM COATED 500MG	5612/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
REPRATGAST TABLET, GASTRO-RESISTANT 20MG	REPRATGAST TABLET, GASTRO-RESISTANT 20MG	6171/23T, 6172/23T	DELORBIS PHARMACEUTICALS LTD	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 B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 200MCG	MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 200MCG	6176/23T	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
MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 400MCG	MIFLONIDE BREEZHALER INHALATION POWDER IN CAPSULES 400MCG	6175/23T	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

LIPOPEN TABLET, FILM COATED 40MG/10MG	LIPOPEN TABLET, FILM COATED 40MG/10MG	4479/23T, 4480/23T, 4481/23T, 4482/23T	ELPEN PHARMACEUTICAL CO INC	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex
LIPOPEN TABLET, FILM COATED 10MG/10MG	LIPOPEN TABLET, FILM COATED 10MG/10MG	4487/23T, 4488/23T, 4489/23T, 4490/23T	ELPEN PHARMACEUTICAL CO INC	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex
LIPOPEN TABLET, FILM COATED 5MG/10MG	LIPOPEN TABLET, FILM COATED 5MG/10MG	4491/23T, 4492/23T, 4493/23T, 4494/23T	ELPEN PHARMACEUTICAL CO INC	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the

				finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex
LIPOPEN TABLET, FILM COATED 20MG/10MG	LIPOPEN TABLET, FILM COATED 20MG/10MG	4483/23T, 4484/23T, 4485/23T, 4486/23T	ELPEN PHARMACEUTICAL CO INC	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex
TEKCIS RADIONUCLIDE GENERATOR 2-50 GBq	TEKCIS RADIONUCLIDE GENERATOR 2-50 GBq	638/23T, 639/23T	CIS BIO INTERNATIONAL	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* B.I.a.2.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
BEROZOL POWDER FOR SOLUTION FOR INJECTION 40MG/VIAL	BEROZOL POWDER FOR SOLUTION FOR INJECTION 40MG/VIAL	5657/23T	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
UNIXAM SOLUTION FOR INJECTION 100MG/ML	UNIXAM SOLUTION FOR INJECTION 100MG/ML	5632/23T	CODAL-SYNTO LIMITED	B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size
MYOVIEW KIT FOR RADIOPHARMACEUTICAL PREPARATION 0.23MG	MYOVIEW KIT FOR RADIOPHARMACEUTICAL PREPARATION 0.23MG	5677/23T	GE HEALTHCARE AS (NYDALEN)	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
ISOTROIN CAPSULE, SOFT 10MG	ISOTROIN CAPSULE, SOFT 10MG	3126/23T	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
ISOTROIN CAPSULE, SOFT 20MG	ISOTROIN CAPSULE, SOFT 20MG	3125/23T	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
ADVECIT CAPSULE, HARD 140MG	ADVECIT CAPSULE, HARD 140MG	5607/23T	DELORBIS PHARMACEUTICALS LTD	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
ADVECIT CAPSULE, HARD 100MG	ADVECIT CAPSULE, HARD 100MG	5608/23T	DELORBIS PHARMACEUTICALS LTD	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
ADVECIT CAPSULE, HARD 250MG	ADVECIT CAPSULE, HARD 250MG	5605/23T	DELORBIS PHARMACEUTICALS LTD	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
ADVECIT CAPSULE, HARD 180MG	ADVECIT CAPSULE, HARD 180MG	5606/23T	DELORBIS PHARMACEUTICALS LTD	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
ADVECIT CAPSULE, HARD 5MG	ADVECIT CAPSULE, HARD 5MG	5610/23T	DELORBIS PHARMACEUTICALS LTD	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
ADVECIT CAPSULE,	ADVECIT CAPSULE,	5609/23T	DELORBIS PHARMACEUTICALS LTD	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation

HARD 20MG	HARD 20MG			
ATARAX TABLET, FILM COATED 25MG	ATARAX TABLET, FILM COATED 25MG	6255/20T	UCB PHARMA SA	C.I.6 z) Change(s) to therapeutic indication(s) Other variation
ATARAX SYRUP 2MG/ML	ATARAX SYRUP 2MG/ML	6254/20T	UCB PHARMA SA	C.I.6 z) Change(s) to therapeutic indication(s) Other variation
ISOTROIN CAPSULE, SOFT 30MG	ISOTROIN CAPSULE, SOFT 30MG	3127/23T	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
HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	5230/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.c.2.z B.II.c.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other variation
HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	5229/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.c.2.z B.II.c.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other variation
PACLITAXEL ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXEL ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	5020/23T	ACCORD HEALTHCARE S.L.U	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)
FLUNOL CAPSULE, HARD 100MG	FLUNOL CAPSULE, HARD 100MG	6539/23T, 6540/23T, 6541/23T, 6542/23T	PHARMA Q 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 - Eur B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - Eur
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	512/23T	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
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	510/23T	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
SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	SELEMYCIN SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	511/23T	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
TOSTRAN GEL 2%	TOSTRAN GEL 2%	6818/22T, 6819/22T, 6820/22T	KYOWA KIRIN HOLDINGS B.V.	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 C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data B.IV.1.c B.IV.1.c - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging 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

HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	2508/22T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol.
HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	2507/22T	GLAXOSMITHKLINE BIOLOGICALS SA	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol.
PEMETREXED SANDOZ CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	PEMETREXED SANDOZ CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	808/23T	SANDOZ PHARMACEUTICALS D.D.	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
IMIGRAN TABLET, FILM COATED 50MG	IMIGRAN TABLET, FILM COATED 50MG	3896/23T, 3897/23T, 3898/23T, 3899/23T	GLAXOSMITHKLINE (IRELAND) 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 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
ADVECIT CAPSULE, HARD 140MG	ADVECIT CAPSULE, HARD 140MG	5473/23T, 5474/23T, 5475/23T, 5476/23T, 5477/23T, 5478/23T	DELORBIS PHARMACEUTICALS LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.4 B.III.1.b.4 - QUALITY

				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
ADVECIT CAPSULE, HARD 100MG	ADVECIT CAPSULE, HARD 100MG	5479/23T, 5480/23T, 5481/23T, 5482/23T, 5483/23T, 5484/23T	DELORBIS PHARMACEUTICALS LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
ADVECIT CAPSULE, HARD 180MG	ADVECIT CAPSULE, HARD 180MG	5467/23T, 5468/23T, 5469/23T, 5470/23T, 5471/23T, 5472/23T	DELORBIS PHARMACEUTICALS LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
ADVECIT CAPSULE, HARD 250MG	ADVECIT CAPSULE, HARD 250MG	5461/23T, 5462/23T, 5463/23T, 5464/23T, 5465/23T, 5466/23T	DELORBIS PHARMACEUTICALS LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active

				substance For an excipient - Eur B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
ADVECIT CAPSULE, HARD 20MG	ADVECIT CAPSULE, HARD 20MG	5485/23T, 5486/23T, 5487/23T, 5488/23T, 5489/23T, 5490/23T	DELORBIS PHARMACEUTICALS LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
ADVECIT CAPSULE, HARD 5MG	ADVECIT CAPSULE, HARD 5MG	5491/23T, 5492/23T, 5493/23T, 5494/23T, 5495/23T, 5496/23T	DELORBIS PHARMACEUTICALS LTD	B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.2 B.III.1.b.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.b.4 B.III.1.b.4 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
OPTODROP EYE DROPS, SOLUTION 2% W/V	OPTODROP EYE DROPS, SOLUTION 2% W/V	3575/23T	RAFARM S.A.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SUGAMMADEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	SUGAMMADEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	6843/23T	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)
PACLITAXEL HOSPIRA CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXEL HOSPIRA CONCENTRATE FOR SOLUTION FOR INFUSION 6MG/ML	3442/23T, 3443/23T, 3444/23T, 3445/23T	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 me B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.e.4.c B.II.e.4.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.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 n
NIMBEX SOLUTION FOR INJECTION OR INFUSION 2MG/ML	NIMBEX SOLUTION FOR INJECTION OR INFUSION 2MG/ML	431/23T, 432/23T, 433/23T	ASPEN PHARMA TRADING LIMITED	B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance
SUTIREM CAPSULE, HARD 12.5MG	SUTIREM CAPSULE, HARD 12.5MG	5596/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SUTIREM CAPSULE, HARD 37.5MG	SUTIREM CAPSULE, HARD 37.5MG	5594/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

SUTIREM CAPSULE, HARD 25MG	SUTIREM CAPSULE, HARD 25MG	5595/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SUTIREM CAPSULE, HARD 50MG	SUTIREM CAPSULE, HARD 50MG	5593/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LOSATHINA KOR TABLET, FILM COATED 100/25MG	LOSATHINA KOR TABLET, FILM COATED 100/25MG	9300/22T	PHARMATHEN S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
LOSATHINA KOR TABLET, FILM COATED 50/12.5MG	LOSATHINA KOR TABLET, FILM COATED 50/12.5MG	9301/22T	PHARMATHEN S.A.	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other obligations and conditions (e.g. agreed wording + QRD template)
AMODUO TABLET 5MG/5MG	AMODUO TABLET 5MG/5MG	5619/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMODUO TABLET 5MG/10MG	AMODUO TABLET 5MG/10MG	5618/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AMODUO TABLET 10MG/10MG	AMODUO TABLET 10MG/10MG	5616/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

AMODUO TABLET 10MG/5MG	AMODUO TABLET 10MG/5MG	5617/23T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SEVOFLURANE-PIRAMAL INHALATION VAPOUR, LIQUID 100% V/V	SEVOFLURANE-PIRAMAL INHALATION VAPOUR, LIQUID 100% V/V	5676/23T	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
OLARTAN TABLET, FILM COATED 10MG	OLARTAN TABLET, FILM COATED 10MG	5155/23T, 5156/23T	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
OLARTAN TABLET, FILM COATED 20MG	OLARTAN TABLET, FILM COATED 20MG	5153/23T, 5154/23T	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
OLARTAN-PLUS TABLET, FILM COATED 20MG/25MG	OLARTAN-PLUS TABLET, FILM COATED 20MG/25MG	5163/23T, 5164/23T	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
OLARTAN-PLUS TABLET, FILM COATED 40MG/25MG	OLARTAN-PLUS TABLET, FILM COATED 40MG/25MG	5159/23T, 5160/23T	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
OLARTAN-PLUS TABLET, FILM COATED 40MG/12.5 MG	OLARTAN-PLUS TABLET, FILM COATED 40MG/12.5 MG	5157/23T, 5158/23T	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
OLARTAN-PLUS TABLET, FILM COATED 20MG/12.5 MG	OLARTAN-PLUS TABLET, FILM COATED 20MG/12.5 MG	5161/23T, 5162/23T	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
OLARTAN TABLET, FILM COATED 40MG	OLARTAN TABLET, FILM COATED 40MG	5151/23T, 5152/23T	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

STATOL TABLET, FILM COATED 20MG	STATOL TABLET, FILM COATED 20MG	4776/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
STATOL TABLET, FILM COATED 40MG	STATOL TABLET, FILM COATED 40MG	4775/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
STATOL TABLET, FILM COATED 10MG	STATOL TABLET, FILM COATED 10MG	4777/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
STATOL TABLET, FILM COATED 5MG	STATOL TABLET, FILM COATED 5MG	4778/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
BENZHEXOL TABLET 5MG	BENZHEXOL TABLET 5MG	6834/23T, 6835/23T	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 corresponding test method
AREMED TABLET, FILM COATED 1MG	AREMED TABLET, FILM COATED 1MG	5447/23T	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
NOPRILAMDT TABLET, FILM COATED 1000MG	NOPRILAMDT TABLET, FILM COATED 1000MG	4953/23T	BIAL-PORTELA & CA, 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
TEMELOR SOLUTION FOR INJECTION 4MG/ML	TEMELOR SOLUTION FOR INJECTION 4MG/ML	4431/23T, 4432/23T	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 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

HALOXEN 20 TABLET 20MG	HALOXEN 20 TABLET 20MG	2788/23T, 2789/23T, 2790/23T	REMEDICA LTD	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation B.II.a.3.z B.II.a.3.z - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other changes
ALUTRIL FORTE TABLET, CHEWABLE 500MG/250 MG	ALUTRIL FORTE TABLET, CHEWABLE 500MG/250 MG	4817/23T	REMEDICA LTD	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)
LAX-TAB TABLET, GASTRO-RESISTANT 5MG	LAX-TAB TABLET, GASTRO-RESISTANT 5MG	4952/23T	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
NIZORAL SHAMPOO 20MG/G	NIZORAL SHAMPOO 20MG/G	4350/23T	STADA ARZNEIMITTEL 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)
NAIREM TABLET, FILM COATED 5MG	NAIREM TABLET, FILM COATED 5MG	9353/22T	DEMO S.A.	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
FLAMATAN TABLET, FILM COATED 12.5MG	FLAMATAN TABLET, FILM COATED 12.5MG	6104/23T	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
EBASTEL TABLET, FILM COATED 10MG	EBASTEL TABLET, FILM COATED 10MG	6001/23T	ALMIRALL S.A.	B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

				New certificate from an already approved manufacturer
TRAVOCORT CREAM	TRAVOCORT CREAM	6462/22T, 6463/22T, 6464/22T, 6465/22T	LEO PHARMA A/S	B.I.b.2.e B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance o B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. C B.I.a.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
ZOVIRAX CREAM 5% W/W	ZOVIRAX CREAM 5% W/W	5436/23T	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)*
DERMOVATE OINTMENT 0.05% W/W	DERMOVATE OINTMENT 0.05% W/W	5433/23T	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)*
BETNOVATE CREAM 0.1% W/W	BETNOVATE CREAM 0.1% W/W	5435/23T	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)*
DERMOVATE CREAM 0.05% W/W	DERMOVATE CREAM 0.05% W/W	5434/23T	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)*

LORYTEC TABLET 10MG	LORYTEC TABLET 10MG	4774/23T	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
METRONIDAZOLE TABLET 200MG	METRONIDAZOLE TABLET 200MG	6151/23T, 6152/23T, 6153/23T	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 - 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)* 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
METRONIDAZOLE TABLET 250MG	METRONIDAZOLE TABLET 250MG	6154/23T, 6155/23T, 6156/23T	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 - 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)* 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
NICORETTE CLEAR PATCH	NICORETTE CLEAR PATCH	5034/21T	JOHNSON & JOHNSON HELLAS	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation

PATCH, TRANSDERMAL 25MG/16h	PATCH, TRANSDERMAL 25MG/16h		CONSUMER AE	
NICORETTE CLEAR PATCH PATCH, TRANSDERMAL 15MG/16h	NICORETTE CLEAR PATCH PATCH, TRANSDERMAL 15MG/16h	5035/21T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
NICORETTE CLEAR PATCH PATCH, TRANSDERMAL 10MG/16h	NICORETTE CLEAR PATCH PATCH, TRANSDERMAL 10MG/16h	5033/21T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation
VORICONAZOLE FRESENIUS KABI POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	VORICONAZOLE FRESENIUS KABI POWDER FOR SOLUTION FOR INFUSION 200MG/VIAL	4946/23T	FRESENIUS KABI HELLAS SINGLE MEMBER 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
XYLOCREAM CREAM (2.5+2.5)% W/W	XYLOCREAM CREAM (2.5+2.5)% W/W	5823/23T, 5824/23T, 5825/23T	VERISFIELD 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.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
REMABIRAT TABLET, FILM COATED 1000MG	REMABIRAT TABLET, FILM COATED 1000MG	4783/23T	REMEDICA LTD	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)
MOVATEC TABLET 15MG	MOVATEC TABLET 15MG	5822/23T	BOEHRINGER INGELHEIM INTERNATIONAL 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
MOVATEC TABLET 7.5MG	MOVATEC TABLET 7.5MG	5821/23T	BOEHRINGER INGELHEIM INTERNATIONAL 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
VAXIGRIPTETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	VAXIGRIPTETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 15MCG/DOSE	5422/23T	SANOFI PASTEUR.	B.I.a.5.a B.I.a.5.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes to the active substance of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza
REMABIRAT TABLET, FILM COATED 250MG	REMABIRAT TABLET, FILM COATED 250MG	4781/23T, 4782/23T	REMEDICA LTD	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s) 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
REMABIRAT TABLET, FILM COATED 500MG	REMABIRAT TABLET, FILM COATED 500MG	4779/23T, 4780/23T	REMEDICA LTD	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s) 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
LEVOMED TABLET 100MG/25MG	LEVOMED TABLET 100MG/25MG	4700/23T	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

LEVOMED TABLET 250MG/25MG	LEVOMED TABLET 250MG/25MG	4699/23T	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
LEVOMED TABLET 100MG/10MG	LEVOMED TABLET 100MG/10MG	4701/23T	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
OPTIVATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	OPTIVATE POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	3351/23T	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
CALCIUM-SANDOZ FORTE EFFERVESCENT TABLET 500MG	CALCIUM-SANDOZ FORTE EFFERVESCENT TABLET 500MG	5702/23T	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
PRIACIN TABLET, FILM COATED 20MG	PRIACIN TABLET, FILM COATED 20MG	5887/23T	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
PRIACIN TABLET, FILM COATED 40MG	PRIACIN TABLET, FILM COATED 40MG	5886/23T	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
PRIACIN TABLET, FILM COATED 10MG	PRIACIN TABLET, FILM COATED 10MG	5888/23T	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 TABLET, FILM COATED 1G	MOXICLAV TABLET, FILM COATED 1G	5877/23T	MEDOCHEMIE LTD	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
MOXICLAV TABLET, FILM COATED 625MG	MOXICLAV TABLET, FILM COATED 625MG	5875/23T	MEDOCHEMIE LTD	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
MOXICLAV TABLET, FILM COATED 375MG	MOXICLAV TABLET, FILM COATED 375MG	5876/23T	MEDOCHEMIE LTD	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release
UNIXAM SOLUTION FOR INJECTION 100MG/ML	UNIXAM SOLUTION FOR INJECTION 100MG/ML	4771/23T	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
LOGIMAX TABLET, PROLONGED-RELEASE 5MG/50MG	LOGIMAX TABLET, PROLONGED-RELEASE 5MG/50MG	3981/23T, 3982/23T	RECORDATI IRELAND LTD	A.5.a A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release 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)
URICHOFEB TABLET, FILM COATED 80MG	URICHOFEB TABLET, FILM COATED 80MG	6535/22T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
URICHOFEB TABLET, FILM COATED 120MG	URICHOFEB TABLET, FILM COATED 120MG	6536/22T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA 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
LATANOPROST DEMO EYE DROPS, SOLUTION 50MCG/ML	LATANOPROST DEMO EYE DROPS, SOLUTION 50MCG/ML	5842/23T, 5843/23T, 5844/23T	DEMO S.A.	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.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
CARBOPLATIN/HOSPIRA SOLUTION FOR INFUSION 10MG/ML	CARBOPLATIN/HOSPIRA SOLUTION FOR INFUSION 10MG/ML	2264/23T	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
VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	VARILRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 2000PFU	5124/23T	GLAXOSMITHKLINE BIOLOGICALS SA	B.II.c.2.z B.II.c.2.z - QUALITY CHANGES - FINISHED PRODUCT - Control of excipients - Change in test procedure for an excipient - Other variation

ZINNAT TABLET, FILM COATED 500MG	ZINNAT TABLET, FILM COATED 500MG	4339/23T	SANDOZ PHARMACEUTICALS D.D.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZINNAT TABLET, FILM COATED 250MG	ZINNAT TABLET, FILM COATED 250MG	4338/23T	SANDOZ PHARMACEUTICALS D.D.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZINNAT GRANULES FOR ORAL SUSPENSION 250MG/5ML	ZINNAT GRANULES FOR ORAL SUSPENSION 250MG/5ML	4340/23T	SANDOZ PHARMACEUTICALS D.D.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L	5667/23T	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	5665/23T	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product
HUMAN ALBUMIN BAXALTA SOLUTION	HUMAN ALBUMIN BAXALTA SOLUTION	5666/23T	BAXALTA INNOVATIONS GMBH	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF -

FOR INFUSION 200G/L	FOR INFUSION 200G/L			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
TRISEQUENS TABLET, FILM COATED	TRISEQUENS TABLET, FILM COATED	4371/23T	NOVO NORDISK 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)*
REFENTA POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION 5MG	REFENTA POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION 5MG	5696/23T	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
REFENTA POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION 2MG	REFENTA POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION 2MG	5697/23T	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
REFENTA POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION 1MG	REFENTA POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION 1MG	5698/23T	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
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	LOSARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET, FILM COATED 100MG/25MG	5437/23T, 5438/23T	KRKA D.D. NOVO MESTO	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
LOSARTAN/HYDROCHLOROTHIAZIDE KRKA	LOSARTAN/HYDROCHLOROTHIAZIDE KRKA	5439/23T, 5440/23T	KRKA D.D. NOVO MESTO	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished

TABLET, FILM COATED 50MG/12.5 MG	TABLET, FILM COATED 50MG/12.5 MG			product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
NEURONTIN CAPSULE, HARD 300MG	NEURONTIN CAPSULE, HARD 300MG	984/23T	UPJOHN HELLAS LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
NEURONTIN CAPSULE, HARD 400MG	NEURONTIN CAPSULE, HARD 400MG	983/23T	UPJOHN HELLAS LTD	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority + QRD update
NEURONTIN CAPSULE, HARD 300MG	NEURONTIN CAPSULE, HARD 300MG	7831/22T	UPJOHN HELLAS 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
NEURONTIN CAPSULE, HARD 400MG	NEURONTIN CAPSULE, HARD 400MG	7830/22T	UPJOHN HELLAS 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
ROSUVASTATIN ACINO TABLET, FILM COATED 40MG	ROSUVASTATIN ACINO TABLET, FILM COATED 40MG	2338/23T	ACINO AG	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 ACINO TABLET, FILM COATED 5MG	ROSUVASTATIN ACINO TABLET, FILM COATED 5MG	2341/23T	ACINO AG	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 ACINO TABLET, FILM COATED 10MG	ROSUVASTATIN ACINO TABLET, FILM COATED 10MG	2340/23T	ACINO AG	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 ACINO TABLET, FILM COATED 20MG	ROSUVASTATIN ACINO TABLET, FILM COATED 20MG	2339/23T	ACINO AG	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
CARDILOR TABLET 200MG	CARDILOR TABLET 200MG	1060/23T, 1061/23T, 1062/23T, 1063/23T, 1064/23T	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 corresponding test method 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.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
COSOPT OPHTHALMIC EYE DROPS, SOLUTION	COSOPT OPHTHALMIC EYE DROPS, SOLUTION	803/23T	VIANEX 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
DORZON EYE DROPS, SOLUTION 2%	DORZON EYE DROPS, SOLUTION 2%	3402/23T, 3403/23T, 3404/23T	SAPIENS 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.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.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
IMODIUM PLUS TABLET 2MG/125MG	IMODIUM PLUS TABLET 2MG/125MG	8187/22T	JOHNSON & JOHNSON HELLAS CONSUMER AE	B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 4000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 4000IU	4944/23T	VENIPHARM	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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 2000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 2000IU	4945/23T	VENIPHARM	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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 6000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 6000IU	4943/23T	VENIPHARM	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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 10000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 10000IU	4941/23T	VENIPHARM	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
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 8000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 8000IU	4942/23T	VENIPHARM	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
RIASTAP POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	RIASTAP POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	5386/23T, 5387/23T	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

PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	PLASMA-LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	4883/23T	BAXTER (HELLAS) EPE	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
MOXICLAV TABLET, FILM COATED 1G	MOXICLAV TABLET, FILM COATED 1G	5690/23T, 5691/23T	MEDOCHEMIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) 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
MOXICLAV TABLET, FILM COATED 625MG	MOXICLAV TABLET, FILM COATED 625MG	5686/23T, 5687/23T	MEDOCHEMIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) 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
MOXICLAV TABLET, FILM COATED 375MG	MOXICLAV TABLET, FILM COATED 375MG	5688/23T, 5689/23T	MEDOCHEMIE LTD	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) 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
INSTILLAGEL GEL	INSTILLAGEL GEL	5845/23T	FARCO-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
SORIL-MED LEMON LOZENGE 3MG	SORIL-MED LEMON LOZENGE 3MG	6123/23T	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
URSOFALK CAPSULE, HARD 250MG	URSOFALK CAPSULE, HARD 250MG	5668/23T	DR. FALK PHARMA GMBH	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
SORIL-MED HONEY & LEMON LOZENGE 0.60MG/1.20MG	SORIL-MED HONEY & LEMON LOZENGE 0.60MG/1.20MG	6060/23T	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
HIREMON EMULSION FOR INJECTION / INFUSION 10MG/ML	HIREMON EMULSION FOR INJECTION / INFUSION 10MG/ML	5099/23T	DEMO 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
HIREMON EMULSION FOR INFUSION 20MG/ML	HIREMON EMULSION FOR INFUSION 20MG/ML	5098/23T	DEMO 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
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG	5646/23T	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
ARCHIFAR POWDER FOR SOLUTION FOR INJECTION	ARCHIFAR POWDER FOR SOLUTION FOR INJECTION	5645/23T	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

/INFUSION 1G	/INFUSION 1G			material/reagent/intermediate used in the manufacturing process of 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	TARGINACT TABLET, PROLONGED-RELEASE 5/2.5MG	1290/23T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	TARGINACT TABLET, PROLONGED-RELEASE 10/5MG	1293/23T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	TARGINACT TABLET, PROLONGED-RELEASE 40/20MG	1291/23T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	TARGINACT TABLET, PROLONGED-RELEASE 20/10MG	1292/23T	MUNDIPHARMA PHARMACEUTICALS LTD	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
SELEX TABLET 5MG	SELEX TABLET 5MG	2586/23T, 2587/23T	CODAL SYNTO LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder 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)
AZITHRAN INJECTABLE POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	AZITHRAN INJECTABLE POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	968/23T	SAPIENS PHARMACEUTICALS LTD	B.II.b.3.b B.II.b.3.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product
SYNTOQUIP TABLET, FILM COATED 1MG	SYNTOQUIP TABLET, FILM COATED 1MG	6423/23T	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
SYNTOQUIP TABLET, FILM COATED 0.25MG	SYNTOQUIP TABLET, FILM COATED 0.25MG	6425/23T	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
SYNTOQUIP TABLET, FILM COATED 2MG	SYNTOQUIP TABLET, FILM COATED 2MG	6422/23T	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
SYNTOQUIP TABLET, FILM COATED 0.5MG	SYNTOQUIP TABLET, FILM COATED 0.5MG	6424/23T	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
SYNTOQUIP TABLET, FILM COATED 5MG	SYNTOQUIP TABLET, FILM COATED 5MG	6421/23T	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
PAZOCTAM POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/ VIAL	PAZOCTAM POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/ VIAL	6388/23T	SAPIENS 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
GABAPENTIN ACCORD	GABAPENTIN ACCORD	6207/23T, 6208/23T	ACCORD HEALTHCARE S.L.U	B.II.e.2.c B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in

CAPSULE, HARD 300MG	CAPSULE, HARD 300MG			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.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	GABAPENTIN ACCORD CAPSULE, HARD 400MG	6205/23T, 6206/23T	ACCORD HEALTHCARE S.L.U	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.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
FINGOLIMOD PHARMASCIENCE CAPSULE, HARD 0.5MG	FINGOLIMOD PHARMASCIENCE CAPSULE, HARD 0.5MG	3320/23T	PHARMASCIENCE INTERNATIONAL 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)
VINORELBINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	VINORELBINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	4866/23T	ACCORD HEALTHCARE S.L.U	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)
CEFURAX POWDER FOR SOLUTION FOR INJECTION /INFUSION 1500MG/VIAL	CEFURAX POWDER FOR SOLUTION FOR INJECTION /INFUSION 1500MG/VIAL	5700/23T	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
CEFURAX POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG/VIAL	CEFURAX POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG/VIAL	5701/23T	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
TEGRETOL SYRUP 100MG/5ML	TEGRETOL SYRUP 100MG/5ML	5639/23T, 5640/23T, 5641/23T	NOVARTIS 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
TEGRETOL TABLET 200MG	TEGRETOL TABLET 200MG	5642/23T, 5643/23T, 5644/23T	NOVARTIS 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
TEGRETOL CR MODIFIED-RELEASE TABLET 400MG	TEGRETOL CR MODIFIED-RELEASE TABLET 400MG	5633/23T, 5634/23T, 5635/23T	NOVARTIS 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
TEGRETOL CR MODIFIED-RELEASE TABLET 200MG	TEGRETOL CR MODIFIED-RELEASE TABLET 200MG	5636/23T, 5637/23T, 5638/23T	NOVARTIS IRELAND LIMITED	B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure
FLIVEN TABLET, FILM COATED 25MG	FLIVEN TABLET, FILM COATED 25MG	3880/23T	DELORBIS PHARMACEUTICALS LTD	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
FLIVEN TABLET, FILM COATED 50MG	FLIVEN TABLET, FILM COATED 50MG	3879/23T	DELORBIS PHARMACEUTICALS LTD	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
ALZEDEM TABLET, FILM COATED 20MG	ALZEDEM TABLET, FILM COATED 20MG	5284/23T, 5285/23T, 5286/23T, 5287/23T	CODAL-SYNTO LIMITED	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a

				manufacturer responsible for importation B.II.b.1.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
ALZEDEM TABLET, FILM COATED 5MG	ALZEDEM TABLET, FILM COATED 5MG	5296/23T, 5297/23T, 5298/23T, 5299/23T	CODAL-SYNTO LIMITED	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation B.II.b.1.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
ALZEDEM TABLET, FILM COATED 15MG	ALZEDEM TABLET, FILM COATED 15MG	5288/23T, 5289/23T, 5290/23T, 5291/23T	CODAL-SYNTO LIMITED	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation B.II.b.1.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
ALZEDEM TABLET, FILM COATED 10MG	ALZEDEM TABLET, FILM COATED 10MG	5292/23T, 5293/23T, 5294/23T, 5295/23T	CODAL-SYNTO LIMITED	B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation B.II.b.1.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
PLATOREL TABLET, FILM COATED 10MG	PLATOREL TABLET, FILM COATED 10MG	2475/23T	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
PLATOREL TABLET, FILM COATED 40MG	PLATOREL TABLET, FILM COATED 40MG	2473/23T	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
PLATOREL TABLET, FILM COATED 20MG	PLATOREL TABLET, FILM COATED 20MG	2474/23T	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
PLATOREL TABLET, FILM COATED 5MG	PLATOREL TABLET, FILM COATED 5MG	2476/23T	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
PLATOREL TABLET, FILM COATED 10MG	PLATOREL TABLET, FILM COATED 10MG	2372/23T	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
PLATOREL TABLET, FILM COATED 40MG	PLATOREL TABLET, FILM COATED 40MG	2370/23T	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
PLATOREL TABLET, FILM COATED 20MG	PLATOREL TABLET, FILM COATED 20MG	2371/23T	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
PLATOREL TABLET, FILM COATED 5MG	PLATOREL TABLET, FILM COATED 5MG	2373/23T	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
PANTOPRAZOLE DELORBIS TABLET, GASTRO-RESISTANT 40MG	PANTOPRAZOLE DELORBIS TABLET, GASTRO-RESISTANT 40MG	6145/23T, 6146/23T	DELORBIS PHARMACEUTICALS LTD	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

				B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	4697/23T, 4698/23T	SAPIENS PHARMACEUTICALS LTD	B.II.g.5.a B.II.g.5.a - QUALITY CHANGES - FINISHED PRODUCT - Design Space and post approval change management protocol - Implementation of changes foreseen in an approved change management protocol - The implementation of the change requires no further supportive data
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	4695/23T, 4696/23T	SAPIENS PHARMACEUTICALS LTD	B.II.g.5.a B.II.g.5.a - QUALITY CHANGES - FINISHED PRODUCT - Design Space and post approval change management protocol - Implementation of changes foreseen in an approved change management protocol - The implementation of the change requires no further supportive data
ACETAZOLAMIDE TABLET 250MG	ACETAZOLAMIDE TABLET 250MG	4784/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	NOPRILAM 125 POWDER FOR ORAL SUSPENSION (125MG/31.25MG)5ML	1581/23T	BIAL-PORTELA & CA, 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
NOPRILAM 250 POWDER FOR ORAL SUSPENSION (250MG/62.5MG)/5ML	NOPRILAM 250 POWDER FOR ORAL SUSPENSION (250MG/62.5MG)/5ML	1580/23T	BIAL-PORTELA & CA, 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
NOPRILAM DT TABLET, FILM COATED 1000MG	NOPRILAM DT TABLET, FILM COATED 1000MG	1582/23T	BIAL-PORTELA & CA, 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
NOPRILAM DT POWDER	NOPRILAM DT POWDER	1584/23T	BIAL-PORTELA & CA, SA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

FOR ORAL SUSPENSION (400MG/57 MG)/5ML	FOR ORAL SUSPENSION (400MG/57 MG)/5ML			MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
NOPRILAM 500 TABLET, FILM COATED (500MG/125MG)	NOPRILAM 500 TABLET, FILM COATED (500MG/125MG)	1583/23T	BIAL-PORTELA & CA, 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
SOLIAN TABLET, FILM COATED 400MG	SOLIAN TABLET, FILM COATED 400MG	4430/23T	SANOFI WINTHROP INDUSTRIE.	B.II.f.1.d B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product
SOLIAN TABLET, FILM COATED 400MG	SOLIAN TABLET, FILM COATED 400MG	3181/23T, 3182/23T	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
BILAZ ORAL SOLUTION 2.5MG/ML	BILAZ ORAL SOLUTION 2.5MG/ML	5501/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	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.
TRIVERAM TABLET, FILM COATED 20MG/5MG/5MG	TRIVERAM TABLET, FILM COATED 20MG/5MG/5MG	3231/23T	LES LABORATOIRES SERVIER	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
TRIVERAM TABLET, FILM COATED 40MG/10MG/10MG	TRIVERAM TABLET, FILM COATED 40MG/10MG/10MG	3234/23T	LES LABORATOIRES SERVIER	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
TRIVERAM TABLET, FILM COATED 20MG/10MG/10MG	TRIVERAM TABLET, FILM COATED 20MG/10MG/10MG	3233/23T	LES LABORATOIRES SERVIER	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
TRIVERAM TABLET, FILM COATED 10MG/5MG/5MG	TRIVERAM TABLET, FILM COATED 10MG/5MG/5MG	3230/23T	LES LABORATOIRES SERVIER	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
TRIVERAM TABLET, FILM COATED 20MG/10MG/5MG	TRIVERAM TABLET, FILM COATED 20MG/10MG/5MG	3232/23T	LES LABORATOIRES SERVIER	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
CHORIOMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	CHORIOMON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	6405/23T, 6406/23T, 6407/23T, 6408/23T, 6409/23T, 6410/23T	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 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)
AZITHRAN TABLET, FILM COATED 500MG	AZITHRAN TABLET, FILM COATED 500MG	912/23T	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
MANTOMED TABLET, FILM COATED 20MG	MANTOMED TABLET, FILM COATED 20MG	4444/23T, 4445/23T, 4446/23T, 4447/23T	MEDOCHEMIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test
MANTOMED TABLET, FILM COATED 10MG	MANTOMED TABLET, FILM COATED 10MG	4448/23T, 4449/23T, 4450/23T, 4451/23T	MEDOCHEMIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test

MANTOMED TABLET, FILM COATED 15MG	MANTOMED TABLET, FILM COATED 15MG	4436/23T, 4437/23T, 4438/23T, 4439/23T	MEDOCHEMIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test
MANTOMED TABLET, FILM COATED 5MG	MANTOMED TABLET, FILM COATED 5MG	4440/23T, 4441/23T, 4442/23T, 4443/23T	MEDOCHEMIE LTD	B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, ex B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	4702/23T	SAPIENS PHARMACEUTICALS LTD	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

VIVIDRIN EYE DROPS 2%	VIVIDRIN EYE DROPS 2%	1031/23T, 1032/23T	DR.GERHARD MANN CHEM.-PHARM. FABRIK GMBH	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.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
BETACORT CREAM	BETACORT CREAM	4758/23T	MEDICAIR BIOSCIENCE LABORATORIES CY LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DERMOVATE OINTMENT 0.05% W/W	DERMOVATE OINTMENT 0.05% W/W	5507/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
MIRENA INTRA UTERINE SYSTEM 52MG (20MCG/24 h)	MIRENA INTRA UTERINE SYSTEM 52MG (20MCG/24 h)	4648/22T	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
BENDAMUSTINE ACCORD POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 2.5MG/ML	BENDAMUSTINE ACCORD POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 2.5MG/ML	4716/23T	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
BENDAMUSTINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	BENDAMUSTINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 25MG/ML	4715/23T	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
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	4244/20T, 4245/20T	ACCORD HEALTHCARE S.L.U	B.III.1 a) 2. Updated certificate from an already approved manufacturer
DULOXETINE ACCORD GASTRO-	DULOXETINE ACCORD GASTRO-	4242/20T, 4243/20T	ACCORD HEALTHCARE S.L.U	B.III.1 a) 2. Updated certificate from an already approved manufacturer

RESISTANT CAPSULE, HARD 30MG	RESISTANT CAPSULE, HARD 30MG			
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 60MG	7384/20T	ACCORD HEALTHCARE S.L.U	B.III.1 b) 2. New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer
DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	DULOXETINE ACCORD GASTRO-RESISTANT CAPSULE, HARD 30MG	7385/20T	ACCORD HEALTHCARE S.L.U	B.III.1 b) 2. New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer
EMFORAL TABLET, FILM COATED 40MG	EMFORAL TABLET, FILM COATED 40MG	5502/23T	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
EMFORAL TABLET, FILM COATED 10MG	EMFORAL TABLET, FILM COATED 10MG	5503/23T	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
TRAVOCORT CREAM	TRAVOCORT CREAM	6940/22T, 6941/22T, 6942/22T, 6943/22T, 8820/22T, 8821/22T, 8822/22T, 8823/22T, 8824/22T	LEO PHARMA A/S	B.II.d.1.f B.II.d.1.f - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product 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.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
EVECET TABLET, PROLONGED-RELEASE 3MG	EVECET TABLET, PROLONGED-RELEASE 3MG	7715/22T	P T HADJIGEORGIOU CO 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
EVECET TABLET, PROLONGED-RELEASE 8MG	EVECET TABLET, PROLONGED-RELEASE 8MG	7713/22T	P T HADJIGEORGIOU CO 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
EVECET TABLET, PROLONGED-RELEASE 4MG	EVECET TABLET, PROLONGED-RELEASE 4MG	7714/22T	P T HADJIGEORGIOU CO 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
EVECET TABLET, PROLONGED-RELEASE 2MG	EVECET TABLET, PROLONGED-RELEASE 2MG	7716/22T	P T HADJIGEORGIOU CO 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
CISPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	CISPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION 1MG/ML	3042/23T, 3043/23T, 3044/23T	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
EVECET TABLET, PROLONGED-RELEASE 8MG	EVECET TABLET, PROLONGED-RELEASE 8MG	5414/20T	P T HADJIGEORGIOU CO LTD	C.I.3 a) Implementation of wording agreed by the competent authority

EVECET TABLET, PROLONGED-RELEASE 3MG	EVECET TABLET, PROLONGED-RELEASE 3MG	5416/20T	P T HADJIGEORGIOU CO LTD	C.I.3 a) Implementation of wording agreed by the competent authority
EVECET TABLET, PROLONGED-RELEASE 4MG	EVECET TABLET, PROLONGED-RELEASE 4MG	5415/20T	P T HADJIGEORGIOU CO LTD	C.I.3 a) Implementation of wording agreed by the competent authority
EVECET TABLET, PROLONGED-RELEASE 2MG	EVECET TABLET, PROLONGED-RELEASE 2MG	5417/20T	P T HADJIGEORGIOU CO LTD	C.I.3 a) Implementation of wording agreed by the competent authority
AMBRISENTAN ACCORD TABLET, FILM COATED 10MG	AMBRISENTAN ACCORD TABLET, FILM COATED 10MG	1501/23T	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
AMBRISENTAN ACCORD TABLET, FILM COATED 5MG	AMBRISENTAN ACCORD TABLET, FILM COATED 5MG	1502/23T	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
LIDOCAINE HYDROCHLORIDE NORIDEM SOLUTION FOR INJECTION 20 MG/ML	LIDOCAINE HYDROCHLORIDE NORIDEM SOLUTION FOR INJECTION 20 MG/ML	1703/23T	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)
LIDOCAINE HYDROCHLORIDE NORIDEM SOLUTION FOR INJECTION 10 MG/ML	LIDOCAINE HYDROCHLORIDE NORIDEM SOLUTION FOR INJECTION 10 MG/ML	1704/23T	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)
ADAGREL TABLET, FILM COATED 75MG	ADAGREL TABLET, FILM COATED 75MG	5531/23T	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
EZETIMIBE +SIMVASTATIN/MYLAN TABLET 10MG/10MG	EZETIMIBE +SIMVASTATIN/MYLAN TABLET 10MG/10MG	4971/23T	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)
RAFAZIL ORAL SOLUTION 1MG/1ML	RAFAZIL ORAL SOLUTION 1MG/1ML	2958/23T, 2959/23T, 2960/23T	RAFARM 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.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 A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical doss
CLOPERAN TABLET 10MG	CLOPERAN TABLET 10MG	6330/23T	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 active substance - Addition of a new specification parameter to the specification with its corresponding test method
CLOPERAN TABLET 10MG	CLOPERAN TABLET 10MG	6101/23T	REMEDICA LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MOXILEN FORTE POWDER FOR ORAL SUSPENSION 250MG/5ML	MOXILEN FORTE POWDER FOR ORAL SUSPENSION 250MG/5ML	5264/23T	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 ORAL SUSPENSION 125MG/5ML	MOXILEN POWDER FOR ORAL SUSPENSION 125MG/5ML	5265/23T	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
FRUMIL TABLET	FRUMIL TABLET	776/22T	SANOFI WINTHROP INDUSTRIE.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
FLUDARA POWDER FOR SOLUTION FOR INJECTION /INFUSION 50MG	FLUDARA POWDER FOR SOLUTION FOR INJECTION /INFUSION 50MG	775/22T	GENZYME EUROPE B.V.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
PRIMPERAN SOLUTION FOR INJECTION 10MG/2ML	PRIMPERAN SOLUTION FOR INJECTION 10MG/2ML	773/22T	SANOFI WINTHROP INDUSTRIE.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
DEPAKINE CHRONO TABLET, PROLONGED-RELEASE 500MG	DEPAKINE CHRONO TABLET, PROLONGED-RELEASE 500MG	771/22T	SANOFI WINTHROP INDUSTRIE.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MAALOX PLUS ORAL SUSPENSION	MAALOX PLUS ORAL SUSPENSION	779/22T	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
LASIX SOLUTION FOR INJECTION 20MG/2ML	LASIX SOLUTION FOR INJECTION 20MG/2ML	774/22T	SANOFI WINTHROP INDUSTRIE.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TARONTAL MODIFIED-RELEASE TABLET 400MG	TARONTAL MODIFIED-RELEASE TABLET 400MG	772/22T	SANOFI-AVENTIS GROUPE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MAALOX ORAL SUSPENSION (22.8+40)MG/ML	MAALOX ORAL SUSPENSION (22.8+40)MG/ML	777/22T	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MAALOX PLUS TABLET, CHEWABLE	MAALOX PLUS TABLET, CHEWABLE	778/22T	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD (OPELLA E.P.E.)	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
MEDODEXAN SOLUTION FOR INJECTION OR	MEDODEXAN SOLUTION FOR INJECTION OR	2985/23T	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

INFUSION 4MG/ML	INFUSION 4MG/ML			medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
DENEX TABLET 100MG	DENEX TABLET 100MG	5136/23T, 5137/23T	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)*
PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	PENTAXIM POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION	2139/23T	SANOFI PASTEUR.	B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)
FLUNOL CAPSULE, HARD 100MG	FLUNOL CAPSULE, HARD 100MG	5169/23T	PHARMA Q 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
LEVOFLOXACIN VIOSER SOLUTION FOR INFUSION 5MG/ML	LEVOFLOXACIN VIOSER SOLUTION FOR INFUSION 5MG/ML	5220/23T	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	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
FOSTER NEXTHALER POWDER FOR INHALATION 100MCG/6MCG	FOSTER NEXTHALER POWDER FOR INHALATION 100MCG/6MCG	4983/23T	CHIESI FARMACEUTICI SPA	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
NUROFEN FOR CHILDREN 4% STRAWBERRY ORAL SUSPENSION 4%	NUROFEN FOR CHILDREN 4% STRAWBERRY ORAL SUSPENSION 4%	8806/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
NUROFEN FOR CHILDREN 4% ORANGE ORAL SUSPENSION 4%	NUROFEN FOR CHILDREN 4% ORANGE ORAL SUSPENSION 4%	8807/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
NUROFEN DURANCE MEDICATED PLASTER 200MG	NUROFEN DURANCE MEDICATED PLASTER 200MG	8805/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
STREPFEN DIRECT CHERRY & MINT OROMUCOSAL SPRAY 8.75MG	STREPFEN DIRECT CHERRY & MINT OROMUCOSAL SPRAY 8.75MG	8803/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
NUROFEN EXPRESS CAPSULE, SOFT 400MG	NUROFEN EXPRESS CAPSULE, SOFT 400MG	8804/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
STREPFEN DIRECT HONEY & LEMON OROMUCOSAL SPRAY, SOLUTION 8.75MG	STREPFEN DIRECT HONEY & LEMON OROMUCOSAL SPRAY, SOLUTION 8.75MG	8801/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done

				by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
STREPFEN ORANGE SUGAR FREE LOZENGE 8.75MG	STREPFEN ORANGE SUGAR FREE LOZENGE 8.75MG	8800/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
STREFEN SUGAR FREE LOZENGE 8.75MG	STREFEN SUGAR FREE LOZENGE 8.75MG	8799/22T	RECKITT BENCKISER HELLAS CHEMICAL ABEE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
NUROFEN LIQUID CAPSULE, SOFT 200MG	NUROFEN LIQUID CAPSULE, SOFT 200MG	8808/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
STREPFEN LOZENGE 8.75MG	STREPFEN LOZENGE 8.75MG	8802/22T	RECKITT BENCKISER HELLAS CHEMICAL ABEE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation

				1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
VERRIA TABLET, FILM COATED 50MG	VERRIA TABLET, FILM COATED 50MG	5097/23T	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
VERRIA TABLET, FILM COATED 200MG	VERRIA TABLET, FILM COATED 200MG	5096/23T	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
CONTROL OC IV POWDER FOR SOLUTION FOR INJECTION 40MG	CONTROL OC IV POWDER FOR SOLUTION FOR INJECTION 40MG	5092/23T	MUNDIPHARMA 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
MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 4G	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 4G	1452/23T	CASEN RECORDATI SL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	1453/23T	CASEN RECORDATI SL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL	1810/23T, 1811/23T	CASEN RECORDATI SL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

SOLUTION IN SACHET 4G	SOLUTION IN SACHET 4G			the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	1820/23T, 1821/23T	CASEN RECORDATI SL	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LYBEREN TABLET, FILM COATED 1000MG	LYBEREN TABLET, FILM COATED 1000MG	5196/23T	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
LYBEREN TABLET, FILM COATED 250MG	LYBEREN TABLET, FILM COATED 250MG	5199/23T	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
LYBEREN TABLET, FILM COATED 750MG	LYBEREN TABLET, FILM COATED 750MG	5197/23T	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
LYBEREN TABLET, FILM COATED 500MG	LYBEREN TABLET, FILM COATED 500MG	5198/23T	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
TICEVIS TABLET 10MG	TICEVIS TABLET 10MG	5200/23T	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
EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	EFLUELDA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE 60MCG/DOSE	150/23T, 151/23T, 152/23T, 153/23T	SANOFI PASTEUR.	B.II.f.1.e B.II.f.1.e - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change to an approved stability protocol B.II.b.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, ex B.II.e.1.b.2 B.II.e.1.b.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological B.II.b.2.c.3 B.II.b.2.c.3 - 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
AGGRASTAT CONCENTRATE FOR SOLUTION FOR INFUSION 0.25MG/ML	AGGRASTAT CONCENTRATE FOR SOLUTION FOR INFUSION 0.25MG/ML	5442/23T	CORREVIO	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
KRATIUM TABLET 5MG	KRATIUM TABLET 5MG	4181/23T	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
KRATIUM TABLET 10MG	KRATIUM TABLET 10MG	4180/23T	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
KRATIUM TABLET 2MG	KRATIUM TABLET 2MG	4182/23T	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
SORIL-MED ORANGE LOZENGE 2MG/0.60MG/1.20MG	SORIL-MED ORANGE LOZENGE 2MG/0.60MG/1.20MG	5125/23T	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
DIVIDOL TABLET, COATED 10MG	DIVIDOL TABLET, COATED 10MG	5029/23T	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
AXETINE POWDER FOR SOLUTION FOR INJECTION /INFUSION 1.5G	AXETINE POWDER FOR SOLUTION FOR INJECTION /INFUSION 1.5G	3592/23T	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 POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG/VIAL	AXETINE POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG/VIAL	3590/23T	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 POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG/VIAL	AXETINE POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG/VIAL	3591/23T	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 POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG/VIAL	AXETINE POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG/VIAL	null	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
VINORELBINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	VINORELBINE ACCORD CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML	2830/23T	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
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 1.5% GLUCOSE	BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 1.5% GLUCOSE	131/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 2.3% GLUCOSE	BICAVERA SOLUTION FOR PERITONEAL DIALYSIS 1.25MMOL/L CALCIUM, 2.3% GLUCOSE	130/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BICAVERA SOLUTION FOR PERITONEAL DIALYSIS	BICAVERA SOLUTION FOR PERITONEAL DIALYSIS	129/23T	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

1.25MMOL/L CALCIUM, 4.25% GLUCOSE	1.25MMOL/L CALCIUM, 4.25% GLUCOSE			
LIOTON 1000 GEL 100000IU/100G	LIOTON 1000 GEL 100000IU/100G	5046/23T	A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE SRL	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PULMICORT NEBULISER SUSPENSION 0.25MG/ML	PULMICORT NEBULISER SUSPENSION 0.25MG/ML	5017/23T, 5018/23T, 5019/23T	ASTRAZENECA 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
PULMICORT NEBULISER SUSPENSION 0.5MG/ML	PULMICORT NEBULISER SUSPENSION 0.5MG/ML	5014/23T, 5015/23T, 5016/23T	ASTRAZENECA 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
VENLAXIN TABLET, PROLONGED-RELEASE 225MG	VENLAXIN TABLET, PROLONGED-RELEASE 225MG	4985/23T, 4986/23T	IASIS PHARMACEUTICALS HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
VENLAXIN TABLET, PROLONG	VENLAXIN TABLET, PROLONG	4987/23T, 4988/23T	IASIS PHARMACEU	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

ED-RELEASE 150MG	ED-RELEASE 150MG		TICALS HELLAS SA	Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in 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
VENLAXIN TABLET, PROLONG ED-RELEASE 75MG	VENLAXIN TABLET, PROLONG ED-RELEASE 75MG	4989/23T, 4990/23T	IASIS PHARMACEU TICALS HELLAS SA	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate from a new manufacturer (replacement or addition) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
LETYBO POWDER FOR SOLUTION FOR INJECTION 50U	LETYBO POWDER FOR SOLUTION FOR INJECTION 50U	4275/23T	CROMA-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
VINORELBI NE ACCORD CONCENT RATE FOR SOLUTION FOR	VINORELBI NE ACCORD CONCENT RATE FOR SOLUTION FOR	4863/22T	ACCORD HEALTHCARE S.L.U	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar

INFUSION 10MG/ML	INFUSION 10MG/ML			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)
LIPIDIL NT TABLET, FILM COATED 145MG	LIPIDIL NT TABLET, FILM COATED 145MG	4887/23T	VIATRIS HEALTHCARE LIMITED.	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
EPIDUO FORTE GEL 0.3%/2.5%	EPIDUO FORTE GEL 0.3%/2.5%	4788/23T	GALDERMA INTERNATIONAL,FRANCE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MEDOPRAZOLE GASTRO-RESISTANT CAPSULE, HARD 20MG	MEDOPRAZOLE GASTRO-RESISTANT CAPSULE, HARD 20MG	5227/23T	MEDOCHEMIE 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
MUCOSOLVAN SYRUP 15MG/5ML	MUCOSOLVAN SYRUP 15MG/5ML	4773/23T	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
MUCOSOLVAN SYRUP 30MG/5ML	MUCOSOLVAN SYRUP 30MG/5ML	4772/23T	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
ZETIVASIM TABLET 10MG/80MG	ZETIVASIM TABLET 10MG/80MG	3022/23T	ANFARM HELLAS 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
ZETIVASIM TABLET	ZETIVASIM TABLET	3024/23T	ANFARM HELLAS S.A.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

10MG/20MG	10MG/20MG			MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ZETIVASIM TABLET 10MG/40MG	ZETIVASIM TABLET 10MG/40MG	3023/23T	ANFARM HELLAS 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
ZETIVASIM TABLET 10MG/10MG	ZETIVASIM TABLET 10MG/10MG	3025/23T	ANFARM HELLAS 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
AZOLAM TABLET 0.5MG	AZOLAM TABLET 0.5MG	5727/23T	SAPIENS PHARMACEUTICALS LTD	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
AZOLAM TABLET 0.25MG	AZOLAM TABLET 0.25MG	5728/23T	SAPIENS PHARMACEUTICALS LTD	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
AZOLAM TABLET 1MG	AZOLAM TABLET 1MG	5726/23T	SAPIENS PHARMACEUTICALS LTD	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
DIOVAN ORAL SOLUTION 3MG/ML	DIOVAN ORAL SOLUTION 3MG/ML	2822/23T	NOVARTIS IRELAND LIMITED	A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active substance or of an excipient
ATODEL TABLET 2MG	ATODEL TABLET 2MG	5777/23T	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
ATODEL TABLET 5MG	ATODEL TABLET 5MG	5776/23T	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
ATODEL TABLET 1MG	ATODEL TABLET 1MG	5778/23T	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
CLOVELEN TABLET, FILM COATED 75MG	CLOVELEN TABLET, FILM COATED 75MG	4351/23T, 4352/23T	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.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)
AMLOBE TABLET 10MG	AMLOBE TABLET 10MG	5658/23T, 5659/23T	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 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)
AMLOBE TABLET 5MG	AMLOBE TABLET 5MG	5660/23T, 5661/23T	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 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)
METRONIDAZOLE B.BRAUN SOLUTION FOR INFUSION 5MG/ML	METRONIDAZOLE B.BRAUN SOLUTION FOR INFUSION 5MG/ML	2878/23T, 2879/23T, 2880/23T, 2881/23T, 2882/23T, 2883/23T, 2884/23T, 2885/23T	B. BRAUN MELSUNGEN AG	B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product* B.II.d.2.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.f B.II.d.2.f - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - To reflect compliance with the Ph.Eur. and remove reference to the outdated internal test method and test method number* 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
METRONIDAZOLE VIOSER	METRONIDAZOLE VIOSER	4530/23T, 4531/23T	VIOSER S.A. PARENTERAL	B.II.e.7.b B.II.e.7.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in

SOLUTION FOR INFUSION 500MG/100 ML	SOLUTION FOR INFUSION 500MG/100 ML		SOLUTIONS INDUSTRY	supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier
SANDIMMUN NEORAL CAPSULE, SOFT 100MG	SANDIMMUN NEORAL CAPSULE, SOFT 100MG	7510/22T, 8488/22T, 8489/22T	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
SANDIMMUN NEORAL CAPSULE, SOFT 25MG	SANDIMMUN NEORAL CAPSULE, SOFT 25MG	7508/22T, 8484/22T, 8485/22T	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
SANDIMMUN NEORAL CAPSULE, SOFT 50MG	SANDIMMUN NEORAL CAPSULE, SOFT 50MG	7509/22T, 8486/22T, 8487/22T	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
SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML	SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML	7511/22T, 8490/22T, 8491/22T	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
CISATRACURIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	CISATRACURIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	4812/23T	ACCORD HEALTHCARE S.L.U	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)
CISATRACURIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	CISATRACURIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	4811/23T	ACCORD HEALTHCARE S.L.U	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)
ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	3989/22T	SANDOZ GMBH	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	3991/22T	SANDOZ GMBH	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH

ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	3990/22T	SANDOZ GMBH	C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	5561/23T, 5562/23T	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 B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SUGAMMADEX ANABIOSIS SOLUTION FOR INJECTION 100MG/ML	SUGAMMADEX ANABIOSIS SOLUTION FOR INJECTION 100MG/ML	3585/23T	ANABIOSIS PC.	B.II.e.5.c B.II.e.5.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/ immunological medicinal products
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 360MG	MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 360MG	1790/23T	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
MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 180MG	MYCOPHENOLIC ACID ACCORD TABLET, GASTRO-RESISTANT 180MG	1791/23T	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
GISOLOM EYE DROPS, SOLUTION 50MCG/ML	GISOLOM EYE DROPS, SOLUTION 50MCG/ML	5259/23T	DELORBIS PHARMACEUTICALS 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
BETASERC TABLET 16MG	BETASERC TABLET 16MG	5223/23T, 5224/23T	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)* 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)
TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	TOPIRAMATE AUROBINDO TABLET, FILM COATED 50MG	4015/23T, 4016/23T	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)*
TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	TOPIRAMATE AUROBINDO TABLET, FILM COATED 100MG	4013/23T, 4014/23T	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)*
TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	TOPIRAMATE AUROBINDO TABLET, FILM COATED 25MG	4017/23T, 4018/23T	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)*
TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	TOPIRAMATE AUROBINDO TABLET, FILM COATED 200MG	4011/23T, 4012/23T	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)*
REPRAT TABLET, GASTRO-RESISTANT 20MG	REPRAT TABLET, GASTRO-RESISTANT 20MG	5424/23T	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
RISPERIDONE-REMEDICA TABLET, FILM COATED 1MG	RISPERIDONE-REMEDICA TABLET, FILM COATED 1MG	5123/23T	REMEDICA LTD	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
RISPERIDONE-REMEDICA TABLET, FILM COATED 2MG	RISPERIDONE-REMEDICA TABLET, FILM COATED 2MG	5122/23T	REMEDICA LTD	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
RISPERIDONE-REMEDICA TABLET, FILM COATED 4MG	RISPERIDONE-REMEDICA TABLET, FILM COATED 4MG	5120/23T	REMEDICA LTD	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
RISPERIDONE-REMEDICA TABLET, FILM COATED 6MG	RISPERIDONE-REMEDICA TABLET, FILM COATED 6MG	5119/23T	REMEDICA LTD	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
RISPERIDONE-REMEDICA TABLET, FILM COATED 3MG	RISPERIDONE-REMEDICA TABLET, FILM COATED 3MG	5121/23T	REMEDICA LTD	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

PLATEL TABLET, FILM COATED 75MG	PLATEL TABLET, FILM COATED 75MG	4387/23T	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)*
SEDISTRESS TABLET, COATED 200MG	SEDISTRESS TABLET, COATED 200MG	4873/23T, 4874/23T	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.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
REPRAT TABLET, GASTRO-RESISTANT 40MG	REPRAT TABLET, GASTRO-RESISTANT 40MG	4937/23T, 4938/23T	DELORBIS PHARMACEUTICALS LTD	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 B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
REPRAT TABLET, GASTRO-RESISTANT 20MG	REPRAT TABLET, GASTRO-RESISTANT 20MG	4939/23T, 4940/23T	DELORBIS PHARMACEUTICALS LTD	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 B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
OXIMEZIN POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G/VIAL	OXIMEZIN POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G/VIAL	3148/23T	NORIDEM ENTERPRISES LTD	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Other changes, including change from single batch size to a range of batch sizes
OXIMEZIN POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	OXIMEZIN POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G/VIAL	3149/23T	NORIDEM ENTERPRISES LTD	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Other changes, including change from single batch size to a range of batch sizes
OXIMEZIN POWDER FOR SOLUTION	OXIMEZIN POWDER FOR SOLUTION	3150/23T	NORIDEM ENTERPRISES LTD	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the

FOR INJECTION /INFUSION 0.5G/VIAL	FOR INJECTION /INFUSION 0.5G/VIAL			finished product - Other changes, including change from single batch size to a range of batch sizes
POTASSIUM IODIDE G.L.PHARMA TABLET 65MG	POTASSIUM IODIDE G.L.PHARMA TABLET 65MG	4810/23T	G.L. PHARMA 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 flavouring material)
LEGOFER ORAL SOLUTION 800(40Fe)MG/15ML	LEGOFER ORAL SOLUTION 800(40Fe)MG/15ML	5925/23T, 5926/23T	COSTAKIS TSISIOS & CO. LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation 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
ZIREX TABLET, FILM COATED 10MG	ZIREX TABLET, FILM COATED 10MG	4816/23T	REMEDICA LTD	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Deletion of pack size(s)
RANOLAZINE ELC TABLET, PROLONGED-RELEASE 375MG	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 375MG	4125/23T, 4126/23T, 4127/23T, 4128/23T, 4129/23T, 4130/23T	ELC GROUP S.R.O.	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.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where r A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compare
RANOLAZINE ELC TABLET, PROLONGED-RELEASE 500MG	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 500MG	4119/23T, 4120/23T, 4121/23T, 4122/23T, 4123/23T, 4124/23T	ELC GROUP S.R.O.	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.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the

				manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where r A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compare
RANOLAZINE ELC TABLET, PROLONGED-RELEASE 750MG	RANOLAZINE ELC TABLET, PROLONGED-RELEASE 750MG	4113/23T, 4114/23T, 4115/23T, 4116/23T, 4117/23T, 4118/23T	ELC GROUP S.R.O.	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.a.1.z B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where r A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate use B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compare
ARIPIPRAZOLE AUROBINDO TABLET 10MG	ARIPIPRAZOLE AUROBINDO TABLET 10MG	3989/23T, 3990/23T	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

ARIPIPRAZOLE AUROBINDO TABLET 15MG	ARIPIPRAZOLE AUROBINDO TABLET 15MG	3987/23T, 3988/23T	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
ARIPIPRAZOLE AUROBINDO TABLET 30MG	ARIPIPRAZOLE AUROBINDO TABLET 30MG	3985/23T, 3986/23T	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
EXEDRAL 25 TABLET, FILM COATED 25MG	EXEDRAL 25 TABLET, FILM COATED 25MG	5087/23T, 5088/23T, 5089/23T	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 A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
AVODART CAPSULE, SOFT 0.5MG	AVODART CAPSULE, SOFT 0.5MG	5138/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
DUODART CAPSULE, HARD	DUODART CAPSULE, HARD	5149/23T	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 200MG	5144/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 25MG	5141/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 100MG	5139/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 50MG	5140/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
INDOXYL GEL 10MG/G+50MG/G	INDOXYL GEL 10MG/G+50MG/G	5145/23T	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	FLUARIX TETRA SUSPENSION FOR INJECTION 15MCG/0.5ML	5150/23T	GLAXOSMITHKLINE BIOLOGICALS SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/100MCG	SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/100MCG	5148/23T	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 5MG	5142/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 2MG	LAMICTAL TABLET, CHEWABLE / DISPERSIBLE 2MG	5143/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/250MCG	SERETIDE DISKUS INHALATION POWDER, PRE-DISPENSED 50MCG/250MCG	5147/23T	GLAXOSMITHKLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
SERETIDE DISKUS	SERETIDE DISKUS	5146/23T	GLAXOSMITHKLINE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name

INHALATION POWDER, PRE-DISPENSED 50MCG/500MCG	INHALATION POWDER, PRE-DISPENSED 50MCG/500MCG		TRADING SERVICES LIMITED.	and/or address of the marketing authorisation holder
NETAXAN EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (3MG/1MG)/ML	NETAXAN EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER (3MG/1MG)/ML	8764/22T	SIFI S.P.A	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
NETAXAN EYE DROPS, SOLUTION (3MG/1MG)/ML	NETAXAN EYE DROPS, SOLUTION (3MG/1MG)/ML	8765/22T	SIFI S.P.A	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
DERMOVATE OINTMENT 0.05% W/W	DERMOVATE OINTMENT 0.05% W/W	4769/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DERMOVATE CREAM 0.05% W/W	DERMOVATE CREAM 0.05% W/W	4770/23T	GLAXOSMITHKLINE (IRELAND) LIMITED	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION IN SACHET 10G	1393/23T	CASEN RECORDATI SL	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION	MACROGOL 4000 CASEN RECORDATI POWDER FOR ORAL SOLUTION	1380/23T	CASEN RECORDATI SL	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent

IN SACHET 4G	IN SACHET 4G			or excipient (when mentioned in the dossier)*
CLOPIDOGREL ACCORD TABLET, FILM COATED 75MG	CLOPIDOGREL ACCORD TABLET, FILM COATED 75MG	4139/23T	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
GENEMENT TABLET, FILM COATED 20MG	GENEMENT TABLET, FILM COATED 20MG	335/21T	SAPIENS PHARMACEUTICALS 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
GENEMENT TABLET, FILM COATED 5MG	GENEMENT TABLET, FILM COATED 5MG	334/21T	SAPIENS PHARMACEUTICALS 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
ROTEQ TABLET, FILM COATED 0.5MG	ROTEQ TABLET, FILM COATED 0.5MG	4808/23T	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
ROTEQ TABLET, FILM COATED 0.25MG	ROTEQ TABLET, FILM COATED 0.25MG	4809/23T	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
ROTEQ TABLET, FILM COATED 5MG	ROTEQ TABLET, FILM COATED 5MG	4805/23T	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
ROTEQ TABLET, FILM COATED 1MG	ROTEQ TABLET, FILM COATED 1MG	4807/23T	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
ROTEQ TABLET, FILM COATED 2MG	ROTEQ TABLET, FILM COATED 2MG	4806/23T	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
CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 8MG/12.5MG	CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 8MG/12.5MG	2624/23T	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/HYDROCHLOROTHIAZIDE KRKA TABLET 16MG/12.5MG	CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 16MG/12.5MG	2623/23T	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/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/25MG	CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/25MG	2621/23T	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/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/12.5 MG	CANDESARTAN/HYDROCHLOROTHIAZIDE KRKA TABLET 32MG/12.5 MG	2622/23T	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
INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 50MG/ML	INJEXATE SOLUTION FOR INJECTION IN PREFILLED SYRINGE 50MG/ML	4646/23T	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
DULCOLAX TABLET, GASTRO-RESISTANT 5MG	DULCOLAX TABLET, GASTRO-RESISTANT 5MG	657/22T	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)
MEDOQUIP TABLET, FILM COATED 5MG	MEDOQUIP TABLET, FILM COATED 5MG	5009/23T	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
MEDOQUIP TABLET, FILM COATED 0.25MG	MEDOQUIP TABLET, FILM COATED 0.25MG	5013/23T	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
MEDOQUIP TABLET, FILM COATED 0.5MG	MEDOQUIP TABLET, FILM COATED 0.5MG	5012/23T	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
MEDOQUIP TABLET, FILM COATED 2MG	MEDOQUIP TABLET, FILM COATED 2MG	5010/23T	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
MEDOQUIP TABLET, FILM COATED 1MG	MEDOQUIP TABLET, FILM COATED 1MG	5011/23T	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
CIPROFLO X TABLET, FILM COATED 250MG	CIPROFLO X TABLET, FILM COATED 250MG	4572/23T	SAPIENS PHARMACEU TICALS 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)
CIPROFLO X TABLET, FILM COATED 500MG	CIPROFLO X TABLET, FILM COATED 500MG	4571/23T	SAPIENS PHARMACEU TICALS 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)
CIPROFLO X TABLET, FILM COATED 750MG	CIPROFLO X TABLET, FILM COATED 750MG	4570/23T	SAPIENS PHARMACEU TICALS 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)
METHOTREXATE/PFIZER TABLET 2.5MG	METHOTREXATE/PFIZER TABLET 2.5MG	1962/23T	PFIZER HELLAS AE	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon
ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	ORIZAL PLUS TABLET, FILM COATED 40/5/25MG	3277/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	ORIZAL PLUS TABLET, FILM COATED 20/5/12.5MG	3280/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	ORIZAL PLUS TABLET, FILM COATED 40/10/25MG	3276/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	ORIZAL PLUS TABLET, FILM COATED 40/5/12.5MG	3279/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ORIZAL PLUS TABLET, FILM COATED 40/10/12.5 MG	ORIZAL PLUS TABLET, FILM COATED 40/10/12.5 MG	3278/23T	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG SA	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	HAVRIX ADULTS SUSPENSION FOR INJECTION 1440 ELISA UNIT/ML	1850/23T, 1851/23T, 1852/23T, 1853/23T, 1854/23T	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 - Addition of a new in-process test and limits A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	HAVRIX JUNIOR SUSPENSION FOR INJECTION 720 ELISA UNIT/0.5ML	1845/23T, 1846/23T, 1847/23T, 1848/23T, 1849/23T	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 - Addition of a new in-process test and limits A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur
CLOVELEN TABLET, FILM COATED 75MG	CLOVELEN TABLET, FILM COATED 75MG	1777/23T	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
ZITHROMAX POWDER FOR ORAL SUSPENSION 200MG/5ML	ZITHROMAX POWDER FOR ORAL SUSPENSION 200MG/5ML	6890/22T	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
ZITHROMAX POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	ZITHROMAX POWDER FOR SOLUTION FOR INFUSION 500MG/VIAL	6889/22T	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
DROLL EAR DROPS SOLUTION 1MG	DROLL EAR DROPS SOLUTION 1MG	8470/22T	GALENICA 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
CANDEPRESS COMP TABLET 8MG/12.5MG	CANDEPRESS COMP TABLET 8MG/12.5MG	4754/23T	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
CANDEPRESS COMP TABLET 16MG/12.5MG	CANDEPRESS COMP TABLET 16MG/12.5MG	4753/23T	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
CANDEPRESS TABLET 32MG	CANDEPRESS TABLET 32MG	4749/23T	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
CANDEPRESS TABLET 8MG	CANDEPRESS TABLET 8MG	4751/23T	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
CANDEPRESS TABLET 4MG	CANDEPRESS TABLET 4MG	4752/23T	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
CANDEPRESS	CANDEPRESS	4750/23T	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.

TABLET 16MG	TABLET 16MG			Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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/1000 MG	VIDELMET TABLET, FILM COATED 50MG/1000 MG	3094/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
VIDELMET TABLET, FILM COATED 50MG/850MG	VIDELMET TABLET, FILM COATED 50MG/850MG	3095/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process
SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION	SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION	3110/23T, 3111/23T	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 - To increase the shelf-life in accordance with ICH guidelines and amend storage conditions (e.g. decrease in temperature to preserve longer shelf-life) 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)
DIAMICRON MODIFIED-RELEASE TABLET 30MG	DIAMICRON MODIFIED-RELEASE TABLET 30MG	10591/20T	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DIAMICRON MODIFIED-RELEASE TABLET 60MG	DIAMICRON MODIFIED-RELEASE TABLET 60MG	10590/20T	LES LABORATOIRES SERVIER	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

MEZAVANT GASTRO-RESISTAN T, PROLONG ED RELEASE TABLETS 1200MG	MEZAVANT GASTRO-RESISTAN T, PROLONG ED RELEASE TABLETS 1200MG	6759/22T	TAKEDA PHARMACEU TICALS INTERNATION AL AG IRELAND BRANCH.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ADACEL SUSPENSI ON FOR INJECTION IN PRE-FILLED SYRINGE	ADACEL SUSPENSI ON FOR INJECTION IN PRE-FILLED SYRINGE	635/23T	SANOFI PASTEUR.	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ALGOVIL TABLET, FILM COATED 600MG	ALGOVIL TABLET, FILM COATED 600MG	2576/23T	IOULIA AND IRENE TSETI PHARMACEU TICAL LABORATORI ES 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
GEMCITABI NE ACCORD POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	GEMCITABI NE ACCORD POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	8324/22T	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
GEMCITABI NE ACCORD POWDER FOR SOLUTION FOR INFUSION 200MG/VIA L	GEMCITABI NE ACCORD POWDER FOR SOLUTION FOR INFUSION 200MG/VIA L	8325/22T	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
CANDIPLA S CREAM 2% W/W	CANDIPLA S CREAM 2% W/W	5165/23T	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

SCABALL TABLET 3MG	SCABALL TABLET 3MG	3611/23T	EPSILON HEALTH (NESTORAS VLACHOS P.C.)	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MYCOZAL CAPSULE, HARD 150MG	MYCOZAL CAPSULE, HARD 150MG	3374/23T, 3375/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MYCOZAL CAPSULE, HARD 150MG	MYCOZAL CAPSULE, HARD 150MG	3374/23T, 3375/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MYCOZAL CAPSULE, HARD 200MG	MYCOZAL CAPSULE, HARD 200MG	3372/23T, 3373/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MYCOZAL CAPSULE, HARD 200MG	MYCOZAL CAPSULE, HARD 200MG	3372/23T, 3373/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MYCOZAL CAPSULE, HARD 50MG	MYCOZAL CAPSULE, HARD 50MG	3378/23T, 3379/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MYCOZAL CAPSULE, HARD 50MG	MYCOZAL CAPSULE, HARD 50MG	3378/23T, 3379/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MYCOZAL CAPSULE, HARD 100MG	MYCOZAL CAPSULE, HARD 100MG	3376/23T, 3377/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
MYCOZAL CAPSULE, HARD 100MG	MYCOZAL CAPSULE, HARD 100MG	3376/23T, 3377/23T	SAPIENS PHARMACEUTICALS LTD	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

ALGOVIL TABLET, FILM COATED 200MG	ALGOVIL TABLET, FILM COATED 200MG	2574/23T	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
ALGOVIL TABLET, FILM COATED 200MG	ALGOVIL TABLET, FILM COATED 200MG	2574/23T	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
FUNGUSTATIN CAPSULE, HARD 150MG	FUNGUSTATIN CAPSULE, HARD 150MG	3792/23T, 4638/23T, 4639/23T, 4640/23T	PFIZER HELLAS AE	B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes
MEZAVANT GASTRO-RESISTANT, PROLONGED RELEASE TABLETS 1200MG	MEZAVANT GASTRO-RESISTANT, PROLONGED RELEASE TABLETS 1200MG	2392/23T	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MEZAVANT GASTRO-RESISTANT, PROLONGED RELEASE TABLETS 1200MG	MEZAVANT GASTRO-RESISTANT, PROLONGED RELEASE TABLETS 1200MG	2392/23T	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH.	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
QUETRA ORAL SOLUTION 100MG/ML	QUETRA ORAL SOLUTION 100MG/ML	4523/23T	REMEDICA LTD	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of

				change(s) for which no new additional data is required to be submitted by the MAH
QUETRA ORAL SOLUTION 100MG/ML	QUETRA ORAL SOLUTION 100MG/ML	4523/23T	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
PEROFEN TABLET, FILM COATED 200MG	PEROFEN TABLET, FILM COATED 200MG	4471/23T	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
PEROFEN TABLET, FILM COATED 200MG	PEROFEN TABLET, FILM COATED 200MG	4471/23T	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
PEROFEN TABLET, COATED 200MG	PEROFEN TABLET, COATED 200MG	4470/23T	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
PEROFEN TABLET, COATED 200MG	PEROFEN TABLET, COATED 200MG	4470/23T	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
PEROFEN 400 TABLET, FILM COATED 400MG	PEROFEN 400 TABLET, FILM COATED 400MG	4468/23T	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
PEROFEN 400 TABLET, FILM COATED 400MG	PEROFEN 400 TABLET, FILM COATED 400MG	4468/23T	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
PEROFEN TABLET, COATED 400MG	PEROFEN TABLET, COATED 400MG	4469/23T	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
PEROFEN TABLET, COATED 400MG	PEROFEN TABLET, COATED 400MG	4469/23T	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
CANDIPLAS CREAM 2% W/W	CANDIPLAS CREAM 2% W/W	3439/23T	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CANDIPLAS CREAM 2% W/W	CANDIPLAS CREAM 2% W/W	3439/23T	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
CANDIPLAS CREAM 2% W/W	CANDIPLAS CREAM 2% W/W	3439/23T	MEDOCHEMIE LTD	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
STILNOX TABLET, FILM COATED 10MG	STILNOX TABLET, FILM COATED 10MG	4390/23T	SANOFI WINTHROP INDUSTRIE.	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
STILNOX TABLET, FILM COATED 10MG	STILNOX TABLET, FILM COATED 10MG	4390/23T	SANOFI WINTHROP INDUSTRIE.	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
STILNOX TABLET, FILM COATED 10MG	STILNOX TABLET, FILM COATED 10MG	4390/23T	SANOFI WINTHROP INDUSTRIE.	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
INTRATECT SOLUTION FOR INFUSION 50G/L	INTRATECT SOLUTION FOR INFUSION 50G/L	1710/23T	BIOTEST PHARMA GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
INTRATECT SOLUTION FOR INFUSION 50G/L	INTRATECT SOLUTION FOR INFUSION 50G/L	1710/23T	BIOTEST PHARMA GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.

INTRATECT SOLUTION FOR INFUSION 100G/L	INTRATECT SOLUTION FOR INFUSION 100G/L	1709/23T	BIOTEST PHARMA GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
INTRATECT SOLUTION FOR INFUSION 100G/L	INTRATECT SOLUTION FOR INFUSION 100G/L	1709/23T	BIOTEST PHARMA GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon.
TRACRIUM INJECTION 10MG/ML	TRACRIUM INJECTION 10MG/ML	4370/23T	ASPEN PHARMA TRADING LIMITED	B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes
REGIOCIT SOLUTION FOR HAEMOFILTRATION	REGIOCIT SOLUTION FOR HAEMOFILTRATION	3008/23T	BAXTER HOLDING B.V.	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
ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 1.5G	ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 1.5G	4239/23T	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
ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG	ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG	4238/23T	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
FINGOLIMOD TECNIGEN CAPSULE, HARD 0.5MG	FINGOLIMOD TECNIGEN CAPSULE, HARD 0.5MG	1496/23T	FARMOZ-SOCIEDADE TECNICO-MEDICINAL,S.A, PORTUGAL	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
DENAZOX TABLET 60MG	DENAZOX TABLET 60MG	4726/23T	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
REPRAT GAST TABLET, GASTRO-RESISTANT 20MG	REPRAT GAST TABLET, GASTRO-RESISTANT 20MG	4605/23T	DELORBIS PHARMACEUTICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
BENCET MOUTH SPRAY OROMUCOSAL SPRAY, SOLUTION (0.15 + 0.5)% w/v	BENCET MOUTH SPRAY OROMUCOSAL SPRAY, SOLUTION (0.15 + 0.5)% w/v	4884/23T, 4885/23T, 4886/23T	NASSINGTON LTD	B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
ZYLORIC TABLET 100MG	ZYLORIC TABLET 100MG	4201/23T	ASPEN PHARMA TRADING LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ZYLORIC TABLET 300MG	ZYLORIC TABLET 300MG	4200/23T	ASPEN PHARMA TRADING LIMITED	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
URSOFALK CAPSULE, HARD 250MG	URSOFALK CAPSULE, HARD 250MG	4729/23T, 4730/23T, 4731/23T, 4732/23T, 4733/23T, 4734/23T, 4735/23T, 4736/23T, 4737/23T	DR. FALK PHARMA GMBH	B.II.b.5.b B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product -

				Addition of a new test(s) and limits B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.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.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
DUINUM TABLET 50MG	DUINUM TABLET 50MG	5285/22T	MEDOCHEMIE LTD	B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms
ALGOVIL TABLET, FILM COATED 400MG	ALGOVIL TABLET, FILM COATED 400MG	2575/23T	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
RETAFORM TABLET, PROLONGED-RELEASE 500MG	RETAFORM TABLET, PROLONGED-RELEASE 500MG	8827/22T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
RETAFORM TABLET, PROLONGED-RELEASE 750MG	RETAFORM TABLET, PROLONGED-RELEASE 750MG	8826/22T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
RETAFORM TABLET, PROLONGED-RELEASE 1000MG	RETAFORM TABLET, PROLONGED-RELEASE 1000MG	8825/22T	WIN MEDICA PHARMACEUTICAL S.A. (TRADING AS WIN MEDICA S.A.)	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or

				supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
PAROXETINE AUROBINDO TABLET, FILM COATED 20MG	PAROXETINE AUROBINDO TABLET, FILM COATED 20MG	4260/23T, 4261/23T	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
PAROXETINE AUROBINDO TABLET, FILM COATED 30MG	PAROXETINE AUROBINDO TABLET, FILM COATED 30MG	4258/23T, 4259/23T	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
MANTOMED TABLET, FILM COATED 20MG	MANTOMED TABLET, FILM COATED 20MG	3179/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM COATED 10MG	MANTOMED TABLET, FILM COATED 10MG	3180/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM COATED 5MG	MANTOMED TABLET, FILM COATED 5MG	3178/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM COATED 15MG	MANTOMED TABLET, FILM COATED 15MG	3177/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM COATED 20MG	MANTOMED TABLET, FILM COATED 20MG	3186/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM	MANTOMED TABLET, FILM	3187/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation

COATED 10MG	COATED 10MG			
MANTOMED TABLET, FILM COATED 15MG	MANTOMED TABLET, FILM COATED 15MG	3184/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOMED TABLET, FILM COATED 5MG	MANTOMED TABLET, FILM COATED 5MG	3185/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
SUGAMMADEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	SUGAMMADEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	4671/23T, 4672/23T, 4673/23T	SAPIENS PHARMACEUTICALS LTD	B.II.d.1.a B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.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.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*
FEMI TABLET 0.250MG/0.035MG	FEMI TABLET 0.250MG/0.035MG	2149/23T, 2150/23T	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 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
OXYNORM CAPSULE, HARD 10MG	OXYNORM CAPSULE, HARD 10MG	2319/22T	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	OXYNORM CAPSULE, HARD 5MG	2318/22T	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	OXYNORM SOLUTION FOR INJECTION OR INFUSION 10MG/ML	2321/22T	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	OXYCONTIN TABLET, PROLONGED-RELEASE 80MG	2315/22T	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	OXYNORM CAPSULE, HARD 20MG	2320/22T	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	OXYCONTIN TABLET, PROLONGED-RELEASE 10MG	2317/22T	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-	OXYCONTIN TABLET, PROLONGED-	2316/22T	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

RELEASE 40MG	RELEASE 40MG			Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure 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 5MG	OXYCONTIN TABLET, PROLONGED-RELEASE 5MG	2311/22T	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	OXYNORM LIQUID ORAL SOLUTION 5MG/5ML	2312/22T	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	OXYCONTIN TABLET, PROLONGED-RELEASE 20MG	2314/22T	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	OXYNORM SOLUTION FOR INJECTION OR INFUSION 50MG/ML	2322/22T	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	OXYNORM CONCENTRATE ORAL SOLUTION 10MG/ML	2313/22T	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
LEFLON TABLET, FILM COATED 100MG	LEFLON TABLET, FILM COATED 100MG	2026/22T	PHARMATHEN S.A.	B.III.1.a.3. Addition of a new CEP [R1-CEP 2007-050-Rev 01] for the active substance "Leflunomide" from an new manufacturer. CEP Holder: "Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, India- 400 013 Mumbai, Maharastra". Site of production: "Cipla Limited, Manufacturing & Research Division, Old Madras Road, Virgonagar District India-560 049 Banglore, Karnataka".
LEFLON TABLET, FILM COATED 20MG	LEFLON TABLET, FILM COATED 20MG	2027/2022T	PHARMATHEN S.A.	B.III.1.a.3. Addition of a new CEP [R1-CEP 2007-050-Rev 01] for the active substance "Leflunomide" from an new manufacturer. CEP Holder: "Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, India- 400 013 Mumbai, Maharastra". Site of production: "Cipla Limited, Manufacturing & Research Division, Old Madras Road, Virgonagar District India-560 049 Banglore, Karnataka".
LEFLON TABLET, FILM COATED 10MG	LEFLON TABLET, FILM COATED 10MG	2028/22T	PHARMATHEN S.A.	B.III.1.a.3. Addition of a new CEP [R1-CEP 2007-050-Rev 01] for the active substance "Leflunomide" from an new manufacturer. CEP Holder: "Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, India- 400 013 Mumbai, Maharastra". Site of production: "Cipla Limited, Manufacturing & Research Division, Old Madras Road, Virgonagar District India-560 049 Banglore, Karnataka".
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	11219-11242/20T	SANDOZ GMBH	A.7 B.III.1.a.3 B.II.a.3.b.2 B.I.b.1.f B.I.b.2.e B.II.a.1.a B.II.a.1.b B.II.a.2.a B.II.d.1.a B.II.d.1.e B.II.d.2.d B.II.d.2.d B.II.d.2.d B.II.d.2.d B.II.d.2.d B.II.e.1.b.1 B.II.e.1.a.1 B.II.e.4.a B.II.b.1.e B.II.b.1.a B.II.b.1.b B.II.b.2.c.2 B.II.b.3.b
ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	11195 - 11218/20T	SANDOZ GMBH	A.7 B.III.1.a.3 B.II.a.3.b.2 B.I.b.1.f B.I.b.2.e B.II.a.1.a B.II.a.1.b B.II.a.2.a B.II.d.1.a B.II.d.1.e B.II.d.2.d B.II.d.2.d B.II.d.2.d B.II.d.2.d B.II.d.2.d B.II.e.1.b.1 B.II.e.1.a.1 B.II.e.4.a B.II.b.1.e B.II.b.1.a B.II.b.1.b B.II.b.2.c.2 B.II.b.3.b

ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	11171 -11194/20T	SANDOZ GMBH	A.7 B.III.1.a.3 B.II.a.3.b.2 B.I.b.1.f B.I.b.2.e B.II.a.1.a B.II.a.1.b B.II.a.2.a B.II.d.1.a B.II.d.1.e B.II.d.2.d B.II.d.2.d B.II.d.2.d B.II.d.2.d B.II.d.2.d B.II.d.2.b B.II.e.1.b.1 B.II.e.1.a.1 B.II.e.4.a B.II.b.1.e B.II.b.1.a B.II.b.1.b B.II.b.2.c.2 B.II.b.3.b
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	6134/15T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	C.I.4 To update sections 4.2, 4.4 and 4.9 of of the SPC to reflect new safety changes which affected the Global Technical Information and the Global Consumer Information
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	1456/15T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	C.I.4. To update section 4.4 of the SmPC – witwith consequential change to the Patient Information Leaflet – in line with update to the Company's Core Safety Information for paracetamol-containing pr
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	11366-11367/19T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.5. a) The activities for which the manufacturer/importer is responsible include batch release B.II.b).2.a). Replacement or addition of a site where batch control/testing takes place
DELTIUS CAPSULE, HARD 50000IU	DELTIUS CAPSULE, HARD 50000IU	10530-10531/19T	ITF HELLAS A.E.	B.II.e.5 Change in pack size of the finished product B.II.e.5 a) 1. Change within the range of the currently approved pack sizes
DELTIUS CAPSULE, HARD 25000IU	DELTIUS CAPSULE, HARD 25000IU	10308/19T	ITF HELLAS A.E.	B.II.e.5 a) 2. Change outside the range of the currently approved pack sizes
LEFLON TABLET, FILM COATED 100MG	LEFLON TABLET, FILM COATED 100MG	8812/19T	PHARMATHEN S.A.	B.III.1.a). 2 Updated certificate from an already approved manufacturer Updated CEP from [R1-CEP 2007-172-Rev 01] to [R1-CEP 2007-172-Rev 02] for the active substance "Leflunomid" .
LEFLON TABLET, FILM COATED 20MG	LEFLON TABLET, FILM COATED 20MG	8811/19T	PHARMATHEN S.A.	B.III.1.a). 2 Updated certificate from an already approved manufacturer Updated CEP from [R1-CEP 2007-172-Rev 01] to [R1-CEP 2007-172-Rev 02] for the active substance "Leflunomid" .
LEFLON TABLET, FILM	LEFLON TABLET, FILM	8810/19T	PHARMATHEN S.A.	B.III.1.a). 2 Updated certificate from an already approved manufacturer

COATED 10MG	COATED 10MG			Updated CEP from [R1-CEP 2007-172-Rev 01] to [R1-CEP 2007-172-Rev 02] for the active substance "Leflunomid" .
ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	7912/19T	SANDOZ GMBH	C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan
ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	7416/19T	SANDOZ GMBH	C.I.11 b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assesment by the competent authority is required
ATORVASTATIN SANDOZ TABLET, FILM COATED 30MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 30MG	7415/19T	SANDOZ GMBH	C.I.3. a) Implementation of wording agreed by the competent authority - Implementation of PSUSA to align Package leaflet in accordance with the CMDh Scientific conclusions and grounds for variation, for the active substance atorvastatin/ezetimibe Procedure no.: PSUSA/00010385/201807
ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	7414/19T	SANDOZ GMBH	C.I.3. a) Implementation of wording agreed by the competent authority - Implementation of PSUSA to align Package leaflet in accordance with the CMDh Scientific conclusions and grounds for variation, for the active substance atorvastatin/ezetimibe Procedure no.: PSUSA/00010385/201807
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	7413/19T	SANDOZ GMBH	C.I.3. a) Implementation of wording agreed by the competent authority - Implementation of PSUSA to align Package leaflet in accordance with the CMDh Scientific conclusions and grounds for variation, for the active substance atorvastatin/ezetimibe Procedure no.: PSUSA/00010385/201807
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	7039-7050/19T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	A.5. b) The activities for which the manufacturer/importer is responsible do not include batch release B.II.b).5. c) Deletion of a non-significant in-process test B.II.b).5. z) Other variation
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	4485-4486/19T	GLAXOSMITHKLINE ΚΑΤΑΝΑΛΩΤΙΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ)	C.I.4. Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. C.I.11. b) Implementation of change(s) w
ATORVASTATIN SANDOZ TABLET,	ATORVASTATIN SANDOZ TABLET,	4029/19T	SANDOZ GMBH	C.I.3. z) Other variation -alignment to PSUFU/00010347/201710/B;

FILM COATED 40MG	FILM COATED 40MG			
ATORVASTATIN SANDOZ TABLET, FILM COATED 30MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 30MG	4028/19T	SANDOZ GMBH	C.I.3. z) Other variation -alignment to PSUFU/00010347/201710/B;
ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	4027/19T	SANDOZ GMBH	C.I.3. z) Other variation -alignment to PSUFU/00010347/201710/B;
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	4026/19T	SANDOZ GMBH	C.I.3. z) Other variation -alignment to PSUFU/00010347/201710/B;
DIAMICRON MODIFIED-RELEASE TABLET 60MG	DIAMICRON MODIFIED-RELEASE TABLET 60MG	3965/19T	LES LABORATOIRES SERVIER	B.II.d.2.d- Change in test procedure tor the finished product-Other changes to a test procedure (including replacemet of addition)
ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	3397/19T	SANDOZ GMBH	C.I.3. z) Other variation -Align PI with PSUFU/00010347/201710/A and adaption to Excipients GL
ATORVASTATIN SANDOZ TABLET, FILM COATED 30MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 30MG	3396/19T	SANDOZ GMBH	C.I.3. z) Other variation -Align PI with PSUFU/00010347/201710/A and adaption to Excipients GL
ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	3395/19T	SANDOZ GMBH	C.I.3. z) Other variation -Align PI with PSUFU/00010347/201710/A and adaption to Excipients GL
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	3394/19T	SANDOZ GMBH	C.I.3. z) Other variation -Align PI with PSUFU/00010347/201710/A and adaption to Excipients GL
ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	2419/19T	SANDOZ GMBH	C.I.3. z) Other variation -Align PI with PSUFU/00010347/201710/A and adaption to Excipients GL
ATORVASTATIN SANDOZ TABLET, FILM	ATORVASTATIN SANDOZ TABLET, FILM	2418/19T	SANDOZ GMBH	C.I.3. z) Other variation -Align PI with PSUFU/00010347/201710/A and adaption to Excipients GL

COATED 30MG	COATED 30MG			
ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	2417/19T	SANDOZ GMBH	C.I.3. z) Other variation -Align PI with PSUFU/00010347/201710/A and adaption to Excipients GL
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	2416/19T	SANDOZ GMBH	C.I.3. z) Other variation -Align PI with PSUFU/00010347/201710/A and adaption to Excipients GL
ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	ERLOTINIB SANDOZ TABLET, FILM COATED 150MG	8771/18T	SANDOZ GMBH	B.I.a.1Change in 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
EVECET TABLET, PROLONGED-RELEASE 8MG	EVECET TABLET, PROLONGED-RELEASE 8MG	8209/18T	P T HADJIGEORGIOU CO LTD	B.I.a.1 c)The proposed manufacturer uses a substantially different route of synthesis or manufacturing conditions, which may have a potential change important quality characteristics of the active substance, such as qualitative and/or quantitative impurity profile requiring qualification, or physicochemical properties impacting on biovailability
EVECET TABLET, PROLONGED-RELEASE 4MG	EVECET TABLET, PROLONGED-RELEASE 4MG	8208/18T	P T HADJIGEORGIOU CO LTD	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
EVECET TABLET, PROLONGED-RELEASE 3MG	EVECET TABLET, PROLONGED-RELEASE 3MG	8207/18T	P T HADJIGEORGIOU CO LTD	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
EVECET TABLET, PROLONGED-RELEASE 2MG	EVECET TABLET, PROLONGED-RELEASE 2MG	8206/18T	P T HADJIGEORGIOU CO LTD	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	7454/18T	SANDOZ GMBH	C.I.3. a) Implementation of wording agreed by the competent authority-alignment to PSUSA/00010347/201710
ATORVASTATIN SANDOZ TABLET, FILM COATED 30MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 30MG	7453/18T	SANDOZ GMBH	C.I.3. a) Implementation of wording agreed by the competent authority-alignment to PSUSA/00010347/201710
ATORVASTATIN SANDOZ	ATORVASTATIN SANDOZ	7452/18T	SANDOZ GMBH	C.I.3. a) Implementation of wording agreed by the competent authority-alignment to PSUSA/00010347/201710

TABLET, FILM COATED 20MG	TABLET, FILM COATED 20MG			
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	7451/18T	SANDOZ GMBH	C.I.3. a) Implementation of wording agreed by the competent authority-alignment to PSUSA/00010347/201710
LEFLON TABLET, FILM COATED 100MG	LEFLON TABLET, FILM COATED 100MG	5662/18T	PHARMATHEN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH Adaptation of the SPC and PIL to the reference product Arava (EU/1/99/118), furthermore implementation of the current QRD template (incl. implementation of the safety features on the packaging, section 17 and 18 [Doc. Ref: CMDh/345/2016; February 2016]) and adaptation to excipient guidelines
LEFLON TABLET, FILM COATED 20MG	LEFLON TABLET, FILM COATED 20MG	5661/18T	PHARMATHEN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH Adaptation of the SPC and PIL to the reference product Arava (EU/1/99/118), furthermore implementation of the current QRD template (incl. implementation of the safety features on the packaging, section 17 and 18 [Doc. Ref: CMDh/345/2016; February 2016]) and adaptation to excipient guidelines
LEFLON TABLET, FILM COATED 10MG	LEFLON TABLET, FILM COATED 10MG	5660/18T	PHARMATHEN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH Adaptation of the SPC and PIL to the reference product Arava (EU/1/99/118), furthermore implementation of the current QRD template (incl. implementation of the safety features on the packaging, section 17 and 18 [Doc. Ref: CMDh/345/2016; February 2016]) and adaptation to excipient guidelines
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	4942/18T	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	C.I.3. a) To update product information in line with PRAC recommendations. The product information has been updated with a warning on the risk of severe skin reactions such as acute generalized exanthematous pustulosis and this adverse drug reaction has been listed with the frequency not known. Consequentially, the PIL and Sections 4.4 and 4.8 of the SPC have been updated.
ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 40MG	638-639/18T	SANDOZ GMBH	C.I. z) Other variation C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH alignment to originator-product Sortis (lastly approved DE/H/XXXX/WS/031) + CMDh_Wording_on_statins_10_2015 + ATD/UID;
ATORVASTATIN SANDOZ TABLET,	ATORVASTATIN SANDOZ TABLET,	636-637/18T	SANDOZ GMBH	C.I. z) Other variation C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH alignment to

FILM COATED 30MG	FILM COATED 30MG			originator-product Sortis (lastly approved DE/H/XXXX/WS/031) + CMDh_Wording_on_statins_10_2015 + ATD/UID;
ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 20MG	634-635/18T	SANDOZ GMBH	C.I. z) Other variation C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH alignment to originator-product Sortis (lastly approved DE/H/XXXX/WS/031) + CMDh_Wording_on_statins_10_2015 + ATD/UID;
ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	ATORVASTATIN SANDOZ TABLET, FILM COATED 10MG	632-633/18T	SANDOZ GMBH	C.I. z) Other variation C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH alignment to originator-product Sortis (lastly approved DE/H/XXXX/WS/031) + CMDh_Wording_on_statins_10_2015 + ATD/UID;
LEFLON TABLET, FILM COATED 100MG	LEFLON TABLET, FILM COATED 100MG	6407/17T	PHARMATHEN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH Adaptation of the SPC and PIL to reference product Arava (CP EU/1/99/118/001-004)
LEFLON TABLET, FILM COATED 20MG	LEFLON TABLET, FILM COATED 20MG	6406/17T	PHARMATHEN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH Adaptation of the SPC and PIL to reference product Arava (CP EU/1/99/118/001-004)
LEFLON TABLET, FILM COATED 10MG	LEFLON TABLET, FILM COATED 10MG	6405/17T	PHARMATHEN S.A.	C.I.2. a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH Adaptation of the SPC and PIL to reference product Arava (CP EU/1/99/118/001-004)
LEFLON TABLET, FILM COATED 100MG	LEFLON TABLET, FILM COATED 100MG	5534/17T	PHARMATHEN S.A.	C.I. z) Other variation Article 5 recommendation to implement the outcome of a PRAC signal recommendation adopted at the 3-6 April 2017 PRAC meeting (EMA/PRAC/221998/2017, 21 April 2017) EPITT No 18787 6 April 2017: Falsely decreased ionised calcium levels section 4.4 of SPC and section 2 of PIL.
LEFLON TABLET, FILM COATED 20MG	LEFLON TABLET, FILM COATED 20MG	5533/17T	PHARMATHEN S.A.	C.I. z) Other variation Article 5 recommendation to implement the outcome of a PRAC signal recommendation adopted at the 3-6 April 2017 PRAC meeting (EMA/PRAC/221998/2017, 21 April 2017) EPITT No 18787 6 April 2017: Falsely decreased ionised calcium levels section 4.4 of SPC and section 2 of PIL.
LEFLON TABLET, FILM COATED 10MG	LEFLON TABLET, FILM COATED 10MG	5532/17T	PHARMATHEN S.A.	C.I. z) Other variation Article 5 recommendation to implement the outcome of a PRAC signal recommendation adopted at the 3-6 April 2017 PRAC meeting (

				EMA/PRAC/221998/2017, 21 April 2017) EPITT No 18787 6 April 2017: Falsely decreased ionised calcium levels section 4.4 of SPC and section 2 of PIL.
EVECET TABLET, PROLONGED-RELEASE 8MG	EVECET TABLET, PROLONGED-RELEASE 8MG	8150, 8153/16T	P T HADJIGEORGIOU CO LTD	A.1. Change in the name and/or address of the MAH A.2. b) for Nationally Authorised Products
EVECET TABLET, PROLONGED-RELEASE 4MG	EVECET TABLET, PROLONGED-RELEASE 4MG	8149, 8152/16T	P T HADJIGEORGIOU CO LTD	A.1. Change in the name and/or address of the MAH A.2. b) for Nationally Authorised Products
EVECET TABLET, PROLONGED-RELEASE 2MG	EVECET TABLET, PROLONGED-RELEASE 2MG	8148, 8151/16T	P T HADJIGEORGIOU CO LTD	A.1. Change in the name and/or address of the MAH A.2. b) for Nationally Authorised Products
EVECET TABLET, PROLONGED-RELEASE 8MG	EVECET TABLET, PROLONGED-RELEASE 8MG	2644/16T	P T HADJIGEORGIOU CO LTD	C.I.3. z) Other variation
EVECET TABLET, PROLONGED-RELEASE 4MG	EVECET TABLET, PROLONGED-RELEASE 4MG	2643/16T	P T HADJIGEORGIOU CO LTD	C.I.3. z) Other variation
EVECET TABLET, PROLONGED-RELEASE 3MG	EVECET TABLET, PROLONGED-RELEASE 3MG	2642/16T	P T HADJIGEORGIOU CO LTD	C.I.3. z) Other variation
EVECET TABLET, PROLONGED-RELEASE 2MG	EVECET TABLET, PROLONGED-RELEASE 2MG	2641/16T	P T HADJIGEORGIOU CO LTD	C.I.3. z) Other variation
EVECET TABLET, PROLONGED-RELEASE 8MG	EVECET TABLET, PROLONGED-RELEASE 8MG	2539/16T	P T HADJIGEORGIOU CO LTD	A.2. b) for Nationally Authorised Products
EVECET TABLET, PROLONGED-RELEASE 4MG	EVECET TABLET, PROLONGED-RELEASE 4MG	2538/16T	P T HADJIGEORGIOU CO LTD	A.2. b) for Nationally Authorised Products
EVECET TABLET, PROLONGED-RELEASE 3MG	EVECET TABLET, PROLONGED-RELEASE 3MG	2537/16T	P T HADJIGEORGIOU CO LTD	A.2. b) for Nationally Authorised Products
EVECET TABLET, PROLONGED-	EVECET TABLET, PROLONGED-	2536/16T	P T HADJIGEORGIOU CO LTD	A.2. b) for Nationally Authorised Products

RELEASE 2MG	RELEASE 2MG			
EVECET TABLET, PROLONGED-RELEASE 8MG	EVECET TABLET, PROLONGED-RELEASE 8MG	1946/16T	P T HADJIGEORGIOU CO LTD	Transfer of marketing Authorisation holder
EVECET TABLET, PROLONGED-RELEASE 4MG	EVECET TABLET, PROLONGED-RELEASE 4MG	1945/16T	P T HADJIGEORGIOU CO LTD	Transfer of marketing Authorisation holder
EVECET TABLET, PROLONGED-RELEASE 3MG	EVECET TABLET, PROLONGED-RELEASE 3MG	1944/16T	P T HADJIGEORGIOU CO LTD	Transfer of marketing Authorisation holder
EVECET TABLET, PROLONGED-RELEASE 2MG	EVECET TABLET, PROLONGED-RELEASE 2MG	1943/16T	P T HADJIGEORGIOU CO LTD	Transfer of marketing Authorisation holder

ADONIS CHRISTOFI

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