

ΕΠΙΣΗΜΗ ΕΦΗΜΕΡΙΔΑ

ΤΗΣ ΚΥΠΡΙΑΚΗΣ ΔΗΜΟΚΡΑΤΙΑΣ

ΚΥΡΙΟ ΜΕΡΟΣ

TMHMA B

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.

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.
 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:	Ρ.Ο.ΒΟΧ 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.

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(Ι)/2001) όπως εκάστοτε τροποποιείται, αποφάσισε την απόσυρση των Φαρμακευτικών Προϊόντων με τα πιο κάτω στοιχεία:

Άρ. Άδειας Κυκλοφορίας	Όνομα Φαρμακευτικού Προϊόντος	Δραστικά Συστατικά	Κάτοχος Άδειας Κυκλοφορίας	Ημερομηνία Έκδοσης Άδειας	Παρτίδα απόσυρσης	Λόγος Απόσυρσης
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	P10064	PHARMAFAST LTD	27/09/2023
CONTROLOC TABLET, GASTRO-RESISTANT 40MG	PI0072	PHARMAFAST LTD	27/09/2023
EFEXOR XR CAPSULE, HARD, PROLONGED- RELEASE 150MG	Pl0057	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	P10059	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

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.) JUBILANT PHARMACEUTICALS NV	Επ' αόριστον
022498	33M0175		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
)23722	42M0016	PHARMAZAC S.A.	Επ' αόριστον
021201	29M0319	PHARMATHEN S.A.	Επ' αόριστον
)21199	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
)22788	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

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.

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 ΠΡΟΪΌΝΤΩΝ

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.

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			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,	AZELASTINE	ELPEN	20/10/2023
	SUSPENSION (137MCG/50MCG)/ACTUATION	HYDROCHLORIDE	PHARMACEUTICAL CO INC	
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

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

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

		004477	07/00/0000
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

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:

		1	I	
Όνομα φαρμακευ- τικού προϊόντος	Αρ. Άδειας Κυκλο- φορίας	Αρ. Τροποποίησης	Κάτοχος Άδειας Κυκλοφορίας	Περιγραφή Τροποποίησης
LETROZOL E TEVA TABLET, FILM COATED 2.5MG	LETROZOL E 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 [1311] lodide as applied by the drug product manufacturer to fully comply with the Ph. Eur
INFANRIX TETRA SUSPENSI ON FOR INJECTION	INFANRIX TETRA SUSPENSI ON FOR INJECTION	9048/23T, 9049/23T, 9050/23T	GLAXOSMITH KLINE 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 SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	BOOSTRIX SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	9045/23T, 9046/23T, 9047/23T	GLAXOSMITH KLINE 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 SUSPENSI ON FOR INJECTION	INFANRIX TETRA SUSPENSI ON FOR INJECTION	9051/23T, 9052/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.I.a).2. a) Minor change in the manufacturing process of the active substance Type IB procedure
PENTAXIM POWDER AND SUSPENSI ON FOR SUSPENSI ON FOR INJECTION	PENTAXIM POWDER AND SUSPENSI ON FOR SUSPENSI ON 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

			I	an avaining t (when mentioned in the
				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)*
				A.7 A.7 - ADMINISTRATIVE
CERTICAN TABLET 0.5MG	CERTICAN TABLET 0.5MG	9781/23T	NOVARTIS IRELAND LIMITED	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing
CERTICAN TABLET 0.75MG	CERTICAN TABLET 0.75MG	9780/23T	NOVARTIS IRELAND LIMITED	sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
MONOPRO ST EYE	MONOPRO ST EYE			A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
DROPS, SOLUTION IN SINGLE DOSE CONTAINE R 50MCG/ML	DROPS, SOLUTION IN SINGLE DOSE CONTAINE R 50MCG/ML	4978/23T	LABORATOIR ES THEA	and/or address of a manufacturer/importer of the 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.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
RUPAFIN TABLET 10MG	RUPAFIN TABLET 10MG	10029/23T, 10030/23T, 10031/23T	J. URIACH Y COMPANIA S.A.	tests or limits applied during the manufacture of the finished product - Tightening of in-process limits
MYCOPHE NOLATE MOFETIL ACCORD TABLET, FILM COATED 500MG	MYCOPHE NOLATE 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
FESOTERO DINE ACCORD TABLET, PROLONG ED-	FESOTERO DINE ACCORD TABLET, PROLONG ED-	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	RELEASE			product - Change in the holding time of
8MG	8MG			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: 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: 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: 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 OROMUCO SAL SPRAY 8.75MG	STREPFEN DIRECT CHERRY & MINT OROMUCO SAL 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
				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
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	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
SYMBICOR T TURBUHAL ER POWDER FOR INHALATIO N 160MCG/4. 5MCG	SYMBICOR T TURBUHAL ER POWDER FOR INHALATIO N 160MCG/4. 5MCG	9368/23T, 9369/23T, 9370/23T	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
SYMBICOR T TURBUHAL ER POWDER FOR INHALATIO N	SYMBICOR T TURBUHAL ER POWDER FOR INHALATIO N	9370/231 9365/23T, 9366/23T, 9367/23T	A AB ASTRAZENEC A AB	approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active

320MCG/9 MCG	320MCG/9 MCG			substance For an excipient - European Pharmacopoeial Certificate of Suitability
MOG	Mee			to the relevant Ph. Eur. Monograph -
				Updated certificate from an already
				approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
0.44510.05				- Submission of a new or updated Ph.
SYMBICOR T	SYMBICOR T			Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
, TURBUHAL	, TURBUHAL			an active substance For a starting
ER	ER			material/reagent/intermediate used in
POWDER FOR	POWDER FOR			the manufacturing process of the active substance For an excipient - European
INHALATIO	INHALATIO			Pharmacopoeial Certificate of Suitability
N 80MCG/4.5	N 80MCG/4.5	0074/00T 0075/00T	ASTRAZENEC	to the relevant Ph. Eur. Monograph -
MCG	MCG	9374/23T, 9375/23T, 9376/23T	A AB	Updated certificate from an already approved manufacturer
			GLAXOSMITH	
			ΚLINE ΚΑΤΑΝΑΛΩΤΙ	
			KATANA/\011 KA ΠΡΟΙΟΝΤΑ	
			ΥΓΕΙΑΣ	
			ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩ	
PANMIGRA	PANMIGRA		ΠΗ ΑΝΩΝΥΜΗ	
N TABLET,	N TABLET,		ETAIPEIA	
FILM COATED	FILM COATED		(GSK CH ΕΛΛΑΣ	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
250MG/250	250MG/250		ΜΟΝΟΠΡΟΣΩ	and/or address of the marketing
MG/65MG	MG/65MG	7355/23T		authorisation holder
			GLAXOSMITH KLINE	
			ΚΑΤΑΝΑΛΩΤΙ	
			ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ	
			ΕΛΛΑΣ	
ZOVIDUO	ZOVIDUO		ΑΝΩΝΥΜΗ	A.1 A.1 - ADMINISTRATIVE
CREAM (50MG/10M	CREAM (50MG/10M		ETAIPEIA (GSK CH	CHANGES - Change in the name and/or address of the marketing
G)/G	Ġ)/G	7359/23T	ΈΛΛΑΣ ΑΕ)	authorisation holder
PANADOL COLD &	PANADOL COLD &		GLAXOSMITH KLINE	
FLU &	FLU &		ΚΑΤΑΝΑΛΩΤΙ	
COUGH	COUGH		ΚΑ ΠΡΟΙΟΝΤΑ	
POWDER FOR ORAL	POWDER FOR ORAL		ΥΓΕΙΑΣ ΕΛΛΑΣ	
SOLUTION	SOLUTION		ΑΝΩΝΥΜΗ	A.1 A.1 - ADMINISTRATIVE
1000MG/20	1000MG/20		ETAIPEIA	CHANGES - Change in the name
0MG/12.2M G	0MG/12.2M G	7358/23T	(GSK CH ΕΛΛΑΣ ΑΕ)	and/or address of the marketing authorisation holder
_	-	·	GLAXOSMITH	
PANADOL	PANADOL		ΚLINE ΚΑΤΑΝΑΛΩΤΙ	
COLD &	COLD &		KA IANA/1211 KA IIPOIONTA	
FLU &	FLU &		ΥΓΕΙΑΣ	
COUGH CAPSULE,	COUGH CAPSULE,		ΕΛΛΑΣ ΑΝΩΝΥΜΗ	A.1 A.1 - ADMINISTRATIVE
HARD	HARD		ETAIPEIA	CHANGES - Change in the name
500MG/100	500MG/100	7357/23T	(GSK CH	and/or address of the marketing
MG/6.1MG	MG/6.1MG	1001/201	EΛΛΑΣ ΑΕ) GLAXOSMITH	authorisation holder
			KLINE	
OTRIVIN	OTRIVIN		ΚΑΤΑΝΑΛΩΤΙ ΚΑ ΠΡΟΙΟΝΤΑ	
ADVANCE	ADVANCE		ΥΓΕΙΑΣ	A.1 A.1 - ADMINISTRATIVE
NASAL	NASAL		ΕΛΛΑΣ	CHANGES - Change in the name
SPRAY, SOLUTION	SPRAY, SOLUTION	7356/23T	ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ	and/or address of the marketing authorisation holder
302011010	301011010	1000/201		

			(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

				C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
AZITHROM				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
YCIN	AZITHROM YCIN ALTAN			in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products
POWDER	POWDER			intended to implement the outcome of a procedure concerning PSUR or PASS,
SOLUTION	SOLUTION		ALTAN	or the outcome of the assessment done by the competent authority under
INFUSION 500MG	INFUSION 500MG	5692/23T	PHARMACEU TICALS S.A.	Articles 45 or 46 of Regulation 1901/2006 - Other variation
				B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT -
RUPAFIN	RUPAFIN			Manufacture - Replacement or addition of a manufacturing site for part or all of
ORAL SOLUTION	ORAL SOLUTION		J. URIACH Y COMPANIA	the manufacturing process of the finished product - Secondary packaging
1MG/ML	1MG/ML	6838/23T	S.A.	site 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
RANOLAZI	RANOLAZI			test B.II.b.4.a B.II.b.4.a - QUALITY
NE ELC TABLET,	NE ELC TABLET,			CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size
PROLONG ED-	PROLONG ED-			(including batch size ranges) of the finished product - Up to 10-fold
RELEASE 750MG	RELEASE 750MG	8036/23T, 8037/23T	ELC GROUP S.R.O.	compared to the originally approved batch size
				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
RANOLAZI NE ELC	RANOLAZI NE ELC			B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT -
TABLET, PROLONG	TABLET, PROLONG			Manufacture - Change in the batch size (including batch size ranges) of the
ED- RELEASE	ED- RELEASE		ELC GROUP	finished product - Up to 10-fold compared to the originally approved
375MG	375MG	8040/23T, 8041/23T	S.R.O.	batch size 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
RANOLAZI	RANOLAZI			beletion of a non-significant in-process test B.II.b.4.a B.II.b.4.a - QUALITY
NE ELC TABLET,	NE ELC TABLET,			CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size
PROLONG ED-	PROLONG ED-			(including batch size ranges) of the finished product - Up to 10-fold
RELEASE 500MG	RELEASE 500MG	8038/23T, 8039/23T	ELC GROUP S.R.O.	compared to the originally approved batch size
BOTOX	BOTOX	2022/227 2224/227		B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of
POWDER FOR	POWDER FOR	3633/23T, 3634/23T, 3635/23T, 3636/23T, 2637/23T, 2638/23T		finished product - Other variation B.I.d.1.c B.I.d.1.c - QUALITY
SOLUTION FOR INJECTION	SOLUTION FOR INJECTION	3637/23T, 3638/23T, 3639/23T, 3640/23T, 3641/23T, 3642/23T,	ABBVIE PHARMACEU	CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage per
200 UNITS	200 UNITS	3643/23T	TICALS S.A.	B.I.b.1.c B.I.b.1.c - QUALITY

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				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
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				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
				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
DOTOY	DOTOY			B.I.b.1.b B.I.b.1.b - QUALITY
BOTOX POWDER	BOTOX POWDER	3655/23T, 3656/23T,		CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in
FOR	FOR	3657/23T, 3658/23T,		the specific
SOLUTION	SOLUTION	3659/23T, 3660/23T,		B.I.b.1.d B.I.b.1.d - QUALITY
FOR	FOR	3661/23T, 3662/23T,	ABBVIE	CHANGES - ACTIVE SUBSTANCE -
INJECTION 50 UNITS	INJECTION 50 UNITS	3663/23T, 3664/23T, 3665/23T	PHARMACEU TICALS S.A.	Control of active substance - Change in the specific
		0000/201	10ALO 0.A.	B.II.d.z B.II.d.z - QUALITY CHANGES -
				FINISHED PRODUCT - Control of
DOTOX	DOTOX			finished product - Other variation
BOTOX POWDER	BOTOX POWDER	3644/23T, 3645/23T,		B.I.d.1.c B.I.d.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE -
FOR	FOR	3646/23T, 3647/23T,		Stability - Change in the re-test
SOLUTION	SOLUTION	3648/23T, 3649/23T,		period/storage per
FOR	FOR	3650/23T, 3651/23T,	ABBVIE	B.I.b.1.c B.I.b.1.c - QUALITY
		3652/23T, 3653/23T,	PHARMACEU	CHANGES - ACTIVE SUBSTANCE -
100 UNITS	100 UNITS	3654/23T	TICALS S.A.	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 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
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				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
VISTABEL POWDER FOR SOLUTION FOR	VISTABEL POWDER FOR SOLUTION FOR	3666/23T, 3667/23T,		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
INJECTION 4 ALLERGAN UNITS/0.1M L	INJECTION 4 ALLERGAN UNITS/0.1M L	3668/23T, 3669/23T, 3670/23T, 3671/23T, 3672/23T, 3673/23T, 3674/23T, 3675/23T, 3676/23T	ABBVIE PHARMACEU TICALS S.A.	the specific B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specific B.I.b.2.a B.I.b.2.a - QUALITY
BOSENTAN ACCORD TABLET, FILM COATED	BOSENTAN ACCORD TABLET, FILM COATED		ACCORD HEALTHCARE	CHANGES - ACTIVE SUBSTANCE - Control 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
125MG BOSENTAN ACCORD TABLET, FILM	125MG BOSENTAN ACCORD TABLET, FILM	9576/23T 9577/23T	S.L.U ACCORD HEALTHCARE S.L.U	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

COATED COATED Staffing material/resequent/intermediate 62.5MG 62.5MG 62.5MG staffing material/resequent/intermediate FLUARIX FLUARIX FLUARIX FLUARIX BLLD.3.8.5LID.3.8.7LID.3.7 SUSPENSI SUSPENSI GLAXOSMITH BLLD.3.8.5LID.3.8.7LID.3.7 NUECTION INJECTION BLLD.3.8.5LID.3.7 FILMARIX NL BL 2569/23T SA BULOGICALS ML B269/23T SA BLIT.1.5.1.5LID.1.1.5.1.7 OULT'Y CHANGES - FINISHED PRODUCT - Stability - Change in the shell-life or storage conditions of the shell-life or storage conditions of the shell-life or sale (supported ty real lime data) BLIT.1.5.1.5LID.1.1.1.0.0LITY FIBRYGA FIBRYGA AND POWDER AND SOLUTION Solution of a manufacturing process of the finished product - As packaged for sale (supported ty real lime data) SULVENT FOR SOLUTION Solution of a sale (supported ty real lime data) SULUTION SOLUTION SOLUTION SOLUTION SOLUTION INEUSIONI SOLUTION SOLUTION SANDOZ SANDOZ COTAPHARM SOLUTION SOLUTION SOLUTION SANDOZ SANDOZ <th></th> <th></th> <th>1</th> <th>Г</th> <th>1</th>			1	Г	1
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SUSPENSI ON FOR INJECTION SUSPENSI ON FOR INJECTION GLAXOSMIL ISMCG/0.5 manufacturing process of the finished product - Minor change in the manufacturing process SA ML ML 8269/23T SA BILLOGICALS SA manufacturing process SA FIBRYGA POWDER	FLUARIX	FLUARIX			
ON FOR INJECTION INJECTION ML ON FOR INJECTION ML GLAXOSMITH BIOLOGICALS SA product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process ML 8269/23T SA manufacture of the finished product - Minor change in the manufacturing process SA ML 8269/23T SA BII.11.b.1 B.II.f.1.b.1 - OUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - As packaged for sale (supported by real time data) B.II.b.11 B.II.b.1.1 B.II.b.1.1 - OUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal product - Replacement or addition of a site where batch control/testing the finished product - Replacement or addition of a site where batch control/testing the finished product - Replacement or addition of a site where batch control/testing takes place AXITINIB/S AXITINIB/S AXITINIB/S AXITINIB/S AXITINIB/S AXITINIB/S AXITINIB/S AXITINIB/S AXITINIB/S AXITINIB/S AXITINIB/S A					
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15MCG/0.5 15MCG/0.5 BIOLOGICALS product - Minor change in the SA ML 8269/23T SA manufacturing process BI.I.f.1.b.1 B.I.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf life of the finished product - Extension of the shelf life of sale (supported by real time data) B.II.b.1 f. BILK.1.b.1 F.QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aspically manufactured) excluding broducts (including thed are aspically manufactured) brod control testing of the finishe					
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FIBRYGA FIBRYGA FIBRYGA 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) FIBRYGA FIBRYGA FIBRYGA POWDER POWDER B.II.b.11 AND AND SoluVENT FOR FOR FOR FOR FOR FOR FOR FOR FOR FOR FOR FOR SOLUFIN Solution or a manufacturing process of the finished product - Site where any mulacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile MUECTION SOLUTION Solution INFUSIONI INFUSIONI Saps2/23T, 9393/23T AXITINIB/S AXITINIB/S AXITINIB/S AXITINIB/S AXITINIB/S SANDOZ TABLET, SANDOZ FILM FILM FILM FILM COATED 5662/23T SMG 5662/23T TABLET, SANDOZ ANDOZ FOR AXITINIB/S AXITINIB/S AXITINIB/S FILM GOATED 5663/23T TABLET, FALET, FILM FALET,					
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VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 1G/VIAL	9670/23T	SAPIENS PHARMACEU TICALS 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
MYCOPHE NOLATE MOFETIL ACCORD TABLET, FILM COATED 500MG	MYCOPHE NOLATE 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

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POWDER & GLAXOSMITH					
				GLAXOSMITH	
			2725/23T		B.II.e).2. z) Other variation

FOR SOL.	FOR SOL.		BIOLOGICALS	
FOR INJ. IN	FOR INJ. IN		SA	
PRE-	PRE-			
FILLED	FILLED			
SYRINGE	SYRINGE			
BOOSTRIX	BOOSTRIX			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR			
INJECTION	INJECTION		GLAXOSMITH	
IN PRE-	IN PRE-		KLINE	
FILLED	FILLED		BIOLOGICALS	
SYRINGE	SYRINGE	2728/23T	SA	B.II.e).2. z) Other variation
FLUARIX	FLUARIX			
TETRA	TETRA			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR		GLAXOSMITH	B.II.e).2. z) Other variation
INJECTION	INJECTION		KLINE	D.n.c
15MCG/0.5	15MCG/0.5	0707/007	BIOLOGICALS	
ML	ML	2727/23T	SA	
VARILRIX	VARILRIX			
POWDER	POWDER			
AND	AND			
SOLVENT	SOLVENT			
FOR	FOR			
SOLUTION	SOLUTION		GLAXOSMITH	PILO 2 7 Change in the creative
				B.II.e.2.z-Change in the specification
FOR	FOR		KLINE	parameters and/or limits of the
INJECTION	INJECTION		BIOLOGICALS	immediate packaging of the finished
2000PFU	2000PFU	2722/23T	SA	product-other variation
HAVRIX	HAVRIX			
ADULTS	ADULTS			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR		GLAXOSMITH	B.II.e.2.z - Change in the specification
INJECTION	INJECTION		KLINE	parameters and/or limits of the
1440 ELISA	1440 ELISA		BIOLOGICALS	immediate packaging of the finished
	1 15 11 7 /5 41	070 / /00T		and deat. Other and stations
UNIT/ML	UNIT/ML	2724/23T	SA	product - Other variation.
UNIT/ML PRIORIX-	UNIT/ML PRIORIX-	2724/231	SA	product - Other Variation.
		2724/231	SA	product - Other Variation.
PRIORIX- TETRA	PRIORIX- TETRA	2724/231	SA	product - Other Variation.
PRIORIX- TETRA POWDER	PRIORIX- TETRA POWDER	2724/231	SA	product - Other Variation.
PRIORIX- TETRA POWDER AND	PRIORIX- TETRA POWDER AND	2724/231	SA	product - Other Variation.
PRIORIX- TETRA POWDER AND SOLVENT	PRIORIX- TETRA POWDER AND SOLVENT	2724/231	SA	product - Other variation.
PRIORIX- TETRA POWDER AND SOLVENT FOR	PRIORIX- TETRA POWDER AND SOLVENT FOR	2724/231	SA	product - Other Variation.
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION	2724/231	SA	product - Other Variation.
PRIORIX- TETRA POWDER AND SOLVENT FOR	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR	2724/231		product - Other Variation.
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION	2724/231	GLAXOSMITH	product - Other Variation.
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR	2724/231		product - Other variation.
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-	2724/231	GLAXOSMITH KLINE	product - Other variation.
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-	2724/231 2729/23T	GLAXOSMITH KLINE	B.II.e).2. z) Other variation
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation B.III.1.a.1 B.III.1.a.1 - QUALITY
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation B.III.1.a.1 B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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.
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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.
PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED	PRIORIX- TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
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		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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
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		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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 -
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 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
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		GLAXOSMITH KLINE BIOLOGICALS	B.II.e).2. z) Other variation 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 -

				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 INTERNATION AL NV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
NAUTISOL TABLET 5MG	NAUTISOL TABLET 5MG	10292/23T	MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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, SUSPENSI ON	DYMISTA NASAL SPRAY, SUSPENSI ON	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 DEUTSCHLAN D 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 PHARMACEU TICALS 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

				monute sture of the finite to the
				manufacture of the finished product - Other changes
BISOLOC TABLET, FILM COATED 2.5MG	BISOLOC TABLET, FILM COATED 2.5MG	10364/23T	SAPIENS PHARMACEU TICALS 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 PHARMACEU TICALS 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	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
OMNIPAQU E SOLUTION FOR INJECTION 350MGI/ML	OMNIPAQU E 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
OMNIPAQU E SOLUTION FOR INJECTION 350MGI/ML	OMNIPAQU E 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
OMNIPAQU E SOLUTION FOR INJECTION <u>300MGI/ML</u> OMNIPAQU	OMNIPAQU E SOLUTION FOR INJECTION 300MGI/ML OMNIPAQU	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 C.I.4 C.I.4 - SAFETY, EFFICACY,
E SOLUTION FOR INJECTION 300MGI/ML	E SOLUTION FOR INJECTION 300MGI/ML	1213/23T, 1214/23T, 1215/23T, 1216/23T, 1217/23T	GE HEALTHCARE AS (NYDALEN)	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package

				Leaflet due to now quality prealining
				Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
MEDODEX	MEDODEX			
AN	AN			
SOLUTION	SOLUTION			
FOR	FOR			
INJECTION	INJECTION			A.2.b A.2.b - ADMINISTRATIVE
OR INFUSION	OR INFUSION		MEDOCHEMIE	CHANGES - Change in the (invented) name of the medicinal product - for
4MG/ML	4MG/ML	10034/23T		Nationally Authorised Products
41010/1012	4100/1012	10034/231		B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
AMOXAPE	AMOXAPE			Stability - Change in the shelf-life or
Ν	Ν			storage conditions of the finished
CAPSULE,	CAPSULE,			product - Extension of the shelf life of
HARD	HARD		REMEDICA	the finished product - As packaged for
250MG	250MG	10027/23T	LTD	sale (supported by real time data)
				B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
AMOXAPE				CHANGES - FINISHED PRODUCT -
N	AMOXAPE N			Stability - Change in the shelf-life or storage conditions of the finished
CAPSULE,	CAPSULE,			product - Extension of the shelf life of
HARD	HARD		REMEDICA	the finished product - As packaged for
500MG	500MG	10026/23T	LTD	sale (supported by real time data)
OLMESART	OLMESART			C.I.11.z C.I.11.z - SAFETY,
AN/HYDRO	AN/HYDRO			EFFICACY, PHARMACOVIGILANCE
CHLOROT	CHLOROT			CHANGES - HUMAN AND
HIAZIDE	HIAZIDE			VETERINARY MEDICINAL
TAD	TAD			PRODUCTS - Introduction of, or
TABLET, FILM	TABLET, FILM			change(s) to, the obligations and conditions of a marketing authorisation,
COATED	COATED			including the risk management plan -
40MG/25M	40MG/25M		TAD PHARMA	Other RMP changes (e.g. agreed
G	G	1947/22T	GMBH	wording + template change)
OLMESART	OLMESART			C.I.11.z C.I.11.z - SAFETY,
AN/HYDRO	AN/HYDRO			EFFICACY, PHARMACOVIGILANCE
CHLOROT	CHLOROT			CHANGES - HUMAN AND
HIAZIDE	HIAZIDE			VETERINARY MEDICINAL
				PRODUCTS - Introduction of, or
TABLET, FILM	TABLET, FILM			change(s) to, the obligations and conditions of a marketing authorisation,
COATED	COATED			including the risk management plan -
20MG/12.5	20MG/12.5		TAD PHARMA	Other RMP changes (e.g. agreed
MG	MG	1944/22T	GMBH	wording + template change)
OLMESART	OLMESART			C.I.11.z C.I.11.z - SAFETY,
AN/HYDRO	AN/HYDRO			EFFICACY, PHARMACOVIGILANCE
CHLOROT	CHLOROT			CHANGES - HUMAN AND
				VETERINARY MEDICINAL
TAD TABLET,	TAD TABLET,			PRODUCTS - Introduction of, or change(s) to, the obligations and
FILM	FILM			conditions of a marketing authorisation,
COATED	COATED			including the risk management plan -
20MG/25M	20MG/25M		TAD PHARMA	Other RMP changes (e.g. agreed
G	G	1945/22T	GMBH	wording + template change)
OLMESART	OLMESART			C.I.11.z C.I.11.z - SAFETY,
AN/HYDRO	AN/HYDRO			EFFICACY, PHARMACOVIGILANCE
CHLOROT	CHLOROT			CHANGES - HUMAN AND
HIAZIDE TAD	HIAZIDE TAD			VETERINARY MEDICINAL PRODUCTS - Introduction of, or
TAD TABLET,	TAD TABLET,			change(s) to, the obligations and
FILM	FILM			conditions of a marketing authorisation,
COATED	COATED			including the risk management plan -
40MG/12.5	40MG/12.5		TAD PHARMA	Other RMP changes (e.g. agreed
MG	MG	1946/22T	GMBH	wording + template change)
				A.2.b A.2.b - ADMINISTRATIVE
BROXIVAN	BROXIVAN			CHANGES - Change in the (invented)
TABLET	TABLET	2756/227	MEDOCHEMIE	name of the medicinal product - for
30MG	30MG	3756/23T	LTD	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 25MC	9926/23T, 9927/23T,	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
25MG TENORMIN TABLET, FILM COATED 100MG	25MG TENORMIN TABLET, FILM COATED 100MG	9928/23T 9920/23T, 9921/23T, 9922/23T	S B.V. ATNAHS PHARMA NETHERLAND S B.V.	batch control/testing takes place 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 A.5.a A.5.a - ADMINISTRATIVE
TENORMIN TABLET, FILM COATED 50MG	TENORMIN TABLET, FILM COATED 50MG	9923/23T, 9924/23T, 9925/23T	ATNAHS PHARMA NETHERLAND S B.V.	CHANGES - Change in the name and/or address of 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
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active substance For an excipient - European
			LABORATOIR ES BESINS	Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
TESTOGEL	TESTOGEL		INTERNATION	Updated certificate from an already
GEL 50MG	GEL 50MG	9467/23T	AL	approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
				the manufacturing process of the active
			LABORATOIR	substance For an excipient - European Pharmacopoeial Certificate of Suitability
			ES BESINS	to the relevant Ph. Eur. Monograph -
TESTOGEL GEL 25MG	TESTOGEL GEL 25MG	9468/23T	INTERNATION AL	Updated certificate from an already approved manufacturer
AZITHROM	AZITHROM			B.II.b.4.a B.II.b.4.a - QUALITY
YCIN JUBILANT	YCIN JUBILANT			CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size
TABLET, FILM	TABLET, FILM		JUBILANT	(including batch size ranges) of the
COATED	COATED		PHARMACEU	finished product - Up to 10-fold compared to the originally approved
500MG AZITHROM	500MG AZITHROM	9790/23T	TICALS NV	batch size B.II.b.4.a B.II.b.4.a - QUALITY
YCIN	YCIN			CHANGES - FINISHED PRODUCT -
JUBILANT TABLET,	JUBILANT TABLET,			Manufacture - Change in the batch size (including batch size ranges) of the
FILM	FILM		JUBILANT	finished product - Up to 10-fold
COATED 250MG	COATED 250MG	9791/23T	PHARMACEU TICALS NV	compared to the originally approved batch size
200100	200100			B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
				to the relevant Ph. Eur. Monograph New certificate from a new
IBUTOMOL				manufacturer (replacement or addition)
TABLET, FILM	TABLET, FILM		PHARMACEU TICAL S.A.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
COATED 200MG/500	COATED 200MG/500		(TRADING AS WIN MEDICA	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion

				an active substance For a starting
				an active substance For a starting material/reagent/intermediate used in
				the manufacturing process of 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
				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
75075	750751		ATNAHS	quality control testing sites) - The
				activities for which the
TABLET 5MG	TABLET 5MG	10271/23T, 10272/23T	NETHERLAND S B.V.	manufacturer/importer is responsible include batch release
JIVIG		102111201, 10212/201	5.0.7.	A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
				and/or address of a
				manufacturer/importer of the 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
ZEOTDU	ZESTRIL		ATNAHS	quality control testing sites) - The
ZESTRIL TABLET	TABLET		PHARMA NETHERLAND	activities for which the manufacturer/importer is responsible
20MG	20MG	10273/23T, 10274/23T	S B.V.	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
				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
7EQTDI	ZESTRIL		ATNAHS PHARMA	quality control testing sites) - The
ZESTRIL TABLET	TABLET		NETHERLAND	activities for which the manufacturer/importer is responsible
10MG	10MG	10269/23T, 10270/23T	S B.V.	include batch release
				B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY
				CHANGES - FINISHED PRODUCT -
PLASMA-	PLASMA-			Container closure system - Change in
LYTE 148	LYTE 148			pack size of the finished product -
(PH 7.4)				Change in the number of units (e.g.
SOLUTION FOR	SOLUTION FOR		BAXTER	tablets, ampoules, etc.) in a pack - Change outside the range of the
INFUSION	INFUSION	7966/23T	(HELLAS) EPE	currently approved pack sizes
		1000/201		sansing approved pack sizes

ESOMEPR AZOLE TAD CAPSULE, GASTRO- RESISTAN T 20MG	ESOMEPR AZOLE TAD CAPSULE, GASTRO- RESISTAN T 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
ESOMEPR AZOLE TAD CAPSULE, GASTRO- RESISTAN T 40MG	ESOMEPR AZOLE TAD CAPSULE, GASTRO- RESISTAN T 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
CLOZAPIN E ACCORD TABLET 100MG	CLOZAPIN E 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
CLOZAPIN E ACCORD TABLET 25MG	CLOZAPIN E 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 SUSPENSI ON FOR INJECTION 15MCG/0.5 ML	FLUARIX TETRA SUSPENSI ON FOR INJECTION 15MCG/0.5 ML	8885/23T	GLAXOSMITH KLINE 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	PRAGIOLA CAPSULE, HARD 75MG PRAGIOLA	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 B.II.b.2.a B.II.b.2.a - QUALITY
CAPSULE, HARD 300MG	CAPSULE, HARD 300MG	9172/23T	KRKA D.D. NOVO MESTO	CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality

			T	
				control testing of the finished product - 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,
PRAGIOLA	PRAGIOLA			batch release arrangements and quality
CAPSULE,	CAPSULE,			control testing of the finished product -
HARD	HARD		KRKA D.D.	Replacement or addition of a site where
150MG	150MG	9173/23T	NOVO MESTO	batch control/testing takes place
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of human medicinal products
COSOPT	COSOPT			intended to implement the outcome of a
IMULTI	IMULTI			procedure concerning PSUR or PASS,
EYE	EYE			or the outcome of the assessment done
DROPS,	DROPS,			by the competent authority under
SOLUTION	SOLUTION			Articles 45 or 46 of Regulation
(20MG/5MG	(20MG/5MG			1901/2006 - Implementation of wording
)/ML)/ML	920/23T	VIANEX S.A	agreed by the competent authority
				A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
COSOPT	COSOPT			and/or address of a
IMULTI	IMULTI			manufacturer/importer of the finished
EYE	EYE			product (including batch release or
DROPS,	DROPS,			quality control testing sites) - The
SOLUTION	SOLUTION			activities for which the
(20MG/5MG	(20MG/5MG	0 405 /00 T		manufacturer/importer is responsible do
)/ML)/ML	2485/23T	VIANEX S.A	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
NAROX	NAROX			responsible for batch release, site
TABLET,	TABLET,			where batch control takes place, or
FILM	FILM		DELORBIS	supplier of a starting material, reagent
COATED	COATED		PHARMACEU	or excipient (when mentioned in the
30MG	30MG	10263/23T	TICALS LTD	dossier)*
				A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer
NAROX	NAROX			responsible for batch release, site
TABLET,	TABLET,			where batch control takes place, or
FILM	FILM		DELORBIS	supplier of a starting material, reagent
COATED 60MG	COATED 60MG	10262/23T	PHARMACEU TICALS LTD	or excipient (when mentioned in the dossier)*
		10202/201		A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer
NAROX	NAROX			responsible for batch release, site
TABLET,	TABLET,			where batch control takes place, or
FILM	FILM		DELORBIS	supplier of a starting material, reagent
COATED	COATED		PHARMACEU	or excipient (when mentioned in the
90MG	90MG	10261/23T	TICALS LTD	dossier)*
				A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
NAROX	NAROX			sites for an active substance,
TABLET,	TABLET,			intermediate or finished product,
FILM	FILM		DELORBIS	packaging site, manufacturer
COATED	COATED	10260/227	PHARMACEU	responsible for batch release, site
120MG	120MG	10260/23T	TICALS LTD	where batch control takes place, or

MLOREX TABLET, TABLET, FLM MLOREX TABLET, TABLET, FLM MLOREX VELORIN TABLET, FLM MLOREX TABLET, FLM MLOREX TABLET, FLM<					evention of a starting material respect
MILOREX TABLET, FLM MILOREX TABLET, SMG50MG MILOREX TABLET, FLM MILOREX TABLET, SMG50MG NILOREX TABLET, SMG50MG NILOREX TAT, A ANINGTRATIVE CHANEE CATED CAREA TAT, A ANINGTRAT					
VELORIN TABLET, FILM VELORIN TABLET, FILM VELORIN VELORIN TABLET, FILM 8352/23T, 8353/23T, 50MG REMEDICA 8352/23T, 8353/23T, 50MG REMEDICA 8352/23T, 8353/23T, 50MG REMEDICA 8352/23T, 8353/23T, 7ALET, TABLET, FILM REMEDICA 8352/23T, 8353/23T, 50MG REMEDICA 8352/23T, 8353/23T, 8353/23T, 7ALET, TABLET, FILM REMEDICA 8352/23T, 8353/23T, 50MG REMEDICA 8352/23T, 8353/23T, 8353/23T, 7ALET, FILM REMEDICA 8352/23T, 8353/23T, 8353/23T, 7ALET, FILM REMEDICA 8352/23T, 8353/23T	-			REMEDICA	B.I.a.1.b B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacture 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.
VELORIN VELORIN VELORIN VELORIN TABLET, FILM SOMG 8352/23T, 8353/23T, REMEDICA REMEDICA EUT. Certificate of suitability or deletion of Ph. Eur. certificate of suitability or deletion of manufacturing sites for an accive substance For an excipient - Eur. A.7. A.7. ADMINISTRATIVE CHANGE VELORIN VELORIN VELORIN VELORIN VELORIN TABLET, FILM COATED 8352/23T, 8353/23T, EITD SOMG 8354/23T VELORIN VELORIN VELORIN VELORIN TABLET, FILM S354/23T SOMG 8354/23T VELORIN VELORIN KURC COATED 8352/23T, 8353/23T, EITD REMEDICA EUR or with a national pharmacopoeia of a Member State - Active substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance to fully comply with the P			9906/23T, 9907/23T		
COATED 50MGCOATED 50MG8352/23T, 8353/23T, 8354/23TREMEDICA LTDEur. or with a national pharmacopoeia of a Member State - Active substanceB.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPH - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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 CHANGE - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes	VELORIN TABLET,	VELORIN TABLET,			 B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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
VELORIN TABLET, FILMVELORIN TABLET, FILMVELORIN FILMVELORI				-	
25MG 25MG 8357/23T LTD reagent or excipient (when mentioned i	VELORIN TABLET, FILM COATED	VELORIN TABLET, FILM COATED	8355/23T, 8356/23T,	REMEDICA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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,

	e dossier)* III.2.a.1 B.III.2.a.1 - QUALITY
CH	HANGES - CEP/TSE/MONOGRAPHS Change to comply with Ph. Eur. or with
ar	national pharmacopoeia of a Member
for	ate - Change of specification(s) of a rmer non EU Pharmacopoeial
	bstance to fully comply with the Ph. Ir. or with a national pharmacopoeia
	a Member State - Active substance .III.1.a.2 B.III.1.a.2 - QUALITY
CH - S Eu	HANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. ur. Certificate of suitability or deletion Ph. Eur. certificate of suitability: For
an	active substance For a starting aterial/reagent/intermediate used in
the	e manufacturing process of the active bstance For an excipient - Eur
- D	7 A.7 - ADMINISTRATIVE CHANGES Deletion of manufacturing sites for an
fini	tive substance, intermediate or ished product, packaging site,
rel	anufacturer responsible for batch lease, site where batch control takes ace, or supplier of a starting material,
rea the	agent or excipient (when mentioned in e dossier)*
CH	III.2.a.1 B.III.2.a.1 - QUALITY HANGES - CEP/TSE/MONOGRAPHS
ar	Change to comply with Ph. Eur. or with national pharmacopoeia of a Member
TABLET, TABLET, for	ate - Change of specification(s) of a mer non EU Pharmacopoeial
COATED COATED 8358/23T, 8359/23T, REMEDICA Eu	bstance to fully comply with the Ph. ur. or with a national pharmacopoeia a Member State - Active substance
В.	II.e.5.a.1 B.II.e.5.a.1 - QUALITY HANGES - FINISHED PRODUCT -
TEKCIS TEKCIS Co	ontainer closure system - Change in the size of the finished product -
LIDE LIDE Ch	hange in the number of units (e.g. blets, ampoules, etc.) in a pack -
OR 2-50 OR 2-50 INTERNATION Ch	nange within the range of the currently
VINCRISTI VINCRISTI	•
SULPHATE SULPHATE PH	.I.4 C.I.4 - SAFETY, EFFICACY, HARMACOVIGILANCE CHANGES - JMAN AND VETERINARY
	EDICINAL PRODUCTS - Change(s) the Summary of Product
OR OR Ch	naracteristics, Labelling or Package eaflet due to new quality, preclinical,
1MG/ML 1MG/ML 8450/23T HELLAS AE clir	nical or pharmacovigilance data .II.b.2.c.2 B.II.b.2.c.2 - QUALITY
CH	HANGES - FINISHED PRODUCT -
bai	anufacture - Change to importer, tch release arrangements and quality
Re	ntrol testing of the finished product - eplacement or addition of a
im im	anufacturer responsible for portation and/or batch release -
B.I	cluding batch control/testing II.b.1.b B.II.b.1.b - QUALITY
	HANGES - FINISHED PRODUCT - anufacture - Replacement or addition
FILM FILM of a	a manufacturing site for part or all of emanufacturing process of the
	ished product - Primary packaging

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				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/80M G	LIPOCAT TABLET, FILM COATED 10MG/80M G	5852/23T, 5853/23T, 5854/23T	ELPEN PHARMACEU TICAL 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 site for part or all of the manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
LIPOCAT TABLET, FILM COATED 10MG/20M G	LIPOCAT TABLET, FILM COATED 10MG/20M G	5858/23T, 5859/23T, 5860/23T	ELPEN PHARMACEU TICAL 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 site for part or all of the 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/10M G	LIPOCAT TABLET, FILM COATED 10MG/10M G	5861/23T, 5862/23T, 5863/23T	ELPEN PHARMACEU TICAL 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

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				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.d.2.a B.II.d.2.a - QUALITY
PRILIGY TABLET,	PRILIGY TABLET,			CHANGES - FINISHED PRODUCT - Control of finished product - Change in
FILM	FILM			test procedure for the finished product -
COATED	COATED	0.400/00 T	MENARINI	Minor changes to an approved test
30MG	30MG	8420/23T	HELLAS S.A.	procedure B.II.d.2.a B.II.d.2.a - QUALITY
PRILIGY	PRILIGY			CHANGES - FINISHED PRODUCT -
TABLET, FILM	TABLET, FILM			Control of finished product - Change in test procedure for the finished product -
COATED	COATED		MENARINI	Minor changes to an approved test
60MG	60MG	8419/23T	HELLAS S.A.	procedure
				C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a procedure concerning PSUR or PASS,
AFENTRAL	AFENTRAL			or the outcome of the assessment done
TABLET,	TABLET,			by the competent authority under
FILM COATED	FILM COATED		MEDOCHEMIE	Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
20MG	20MG	9145/23T	LTD	agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a procedure concerning PSUR or PASS,
AFENTRAL	AFENTRAL			or the outcome of the assessment done
TABLET,	TABLET,			by the competent authority under
FILM COATED	FILM COATED		MEDOCHEMIE	Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
30MG	30MG	9144/23T	LTD	agreed by the competent authority
CANFOTEN	CANFOTEN			B.II.e.7.b B.II.e.7.b - QUALITY
CANESTEN CUTANEO	CANESTEN CUTANEO			CHANGES - FINISHED PRODUCT - Container closure system - Change in
US	US			supplier of packaging components or
SOLUTION 1%	SOLUTION 1%	10143/23T	BAYER HELLAS ABEE	devices (when mentioned in the dossier) - Replacement or addition of a supplier
HYDROXY	HYDROXY			A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
UINE SULFATE	UINE SULFATE			and/or address of a manufacturer/importer of the finished
ACCORD	ACCORD			product (including batch release or
TABLET, FILM	TABLET, FILM		ACCORD	quality control testing sites) - The activities for which the
COATED	COATED		HEALTHCARE	manufacturer/importer is responsible do
200MG	200MG	9502/23T	S.L.U	not include batch release B.II.d.1.c B.II.d.1.c - QUALITY
				CHANGES - FINISHED PRODUCT -
VALSARTA	VALSARTA			Control of finished product - Change in
N JUBILANT	N JUBILANT			the specification parameters and/or limits of the finished product - Addition
TABLET,	TABLET,			of a new specification parameter to the
FILM COATED	FILM COATED	9707/23T, 9708/23T,	JUBILANT PHARMACEU	specification with its correspo B.I.b.1.c B.I.b.1.c - QUALITY
80MG	80MG	9707/231, 9708/231, 9709/23T, 9710/23T	TICALS NV	CHANGES - ACTIVE SUBSTANCE -
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			0744/007 0740/007		
40MG 40MG 9713/231, 9714/231 HCALS NV CHANGES - CEP/TSE/MONOGRAPHS	40MG	40MG	9713/23T, 9714/23T	TICALS NV	CHANGES - CEP/TSE/MONOGRAPHS

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				- Submission of a new 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	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	SUTIREM CAPSULE, HARD 50MG SUTIREM	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 - B.I.a.2.e B.I.a.2.e - QUALITY
CAPSULE, HARD 37.5MG	CAPSULE, HARD 37.5MG	10050/23T, 10051/23T	REMEDICA LTD	CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active

HAVRIX	HAVRIX			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 -
JUNIOR SUSPENSI ON FOR INJECTION 720 ELISA UNIT/0.5ML	JUNIOR SUSPENSI ON FOR INJECTION 720 ELISA UNIT/0.5ML	2718/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.e.z - Change in container closure system of the Finished Product - Other variation
HAVRIX ADULTS SUSPENSI ON FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSI ON FOR INJECTION 1440 ELISA UNIT/ML	2717/23T	GLAXOSMITH KLINE BIOLOGICALS SA	B.II.e.z - Change in container closure system of the Finished Product - Other variation
ENGERIX-B PEDIATRIC SUSPENSI ON FOR INJECTION 10MCG/0.5 ML	ENGERIX-B PEDIATRIC SUSPENSI ON FOR INJECTION 10MCG/0.5 ML	2720/23T	GLAXOSMITH KLINE 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	GLAXOSMITH KLINE BIOLOGICALS SA	z) Other variation
ENGERIX-B SUSPENSI ON FOR INJECTION 20MCG/1M L	ENGERIX-B SUSPENSI ON FOR INJECTION 20MCG/1M L	2719/23T	GLAXOSMITH KLINE 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	GLAXOSMITH KLINE 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 HAVRIX ADULTS	PRIORIX POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE- FILLED SYRINGE HAVRIX ADULTS	2715/23T 1195/23T	GLAXOSMITH KLINE BIOLOGICALS SA GLAXOSMITH KLINE	B.II.e). z) Other variation B.IV.1.c - Change of a measuring or administration device - Addition or

SUSPENSI NIJECTION SUSPENSI NIJECTION SUSPENSI SA replacement of a device which is an image rate part of the primary packaging. INTEGRATION NIJECTION SA INTERNIZ CLAXOSNITH KLINE SA INTARINIX CLAXOSNITH KLINE B.V.1.0. INTARINIX CLAXOSNITH KLINE B.V.1.0. SUSPENSI SUSPENS			1		
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1440 ELISA1440 ELISA4058/23T, 4059/23T, 4060/23TBIOLOGICALSprocedure (including replacement or addition)					B.II.c).2. d) Other changes to a test
UNIT/ML UNIT/ML 4060/23T SA addition)	1440 ELISA	1440 ELISA		BIOLOGICALS	
HAVRIX HAVRIX 4051/23T, 4052/23T, B.II.c).2. d) Other changes to a test		UNIT/ML	4060/23T	SA	addition)
	HAVRIX	HAVRIX			
JUNIOR JUNIOR 4053/23T, 4054/23T, GLAXOSMITH procedure (including replacement or					procedure (including replacement or
SUSPENSI SUSPENSI 4055/23T KLINE addition)	SUSPENSI	SUSPENSI	4055/23T	KLINE	addition)

ON FOR	ON FOR		BIOLOGICALS	
INJECTION	INJECTION		SA	
720 ELISA	720 ELISA			
UNIT/0.5ML	UNIT/0.5ML			
BOOSTRIX	BOOSTRIX			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR			
INJECTION	INJECTION		GLAXOSMITH	
		4004/007 4000/007		
IN PRE-	IN PRE-	4031/23T, 4032/23T,	KLINE	B.II.d).2. d) Other changes to a test
FILLED	FILLED	4033/23T, 4034/23T,	BIOLOGICALS	procedure (including replacement or
SYRINGE	SYRINGE	4035/23T	SA	addition)
INFANRIX	INFANRIX			
TETRA	TETRA		GLAXOSMITH	
SUSPENSI	SUSPENSI	4036/23T, 4037/23T,	KLINE	B.II.d).2. d) Other changes to a test
ON FOR	ON FOR	4038/23T, 4039/23T,	BIOLOGICALS	procedure (including replacement or
INJECTION	INJECTION	4040/23T	SA	addition)
PENTAXIM	PENTAXIM			
POWDER	POWDER			
AND	AND			
SUSPENSI	SUSPENSI			
				P b 2 z) lodoto the gue!!!
ON FOR	ON FOR			B.I.b.2.z) Update the qualification
SUSPENSI	SUSPENSI		04105	protocol already registered for the
ON FOR	ON FOR		SANOFI	internal PRP-T reference standard
INJECTION	INJECTION	1201/23T	PASTEUR.	batch used for
TETRAXIM	TETRAXIM			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR			
INJECTION	INJECTION			
IN PRE-	IN PRE-			
FILLED	FILLED		SANOFI	Deletion of an in-process test
SYRINGE	SYRINGE	7490/22T	PASTEUR.	(intradermal test) applied during
PENTAXIM	PENTAXIM		TAULUN.	
POWDER	POWDER			
AND	AND			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR		SANOFI	the manufacture of the Purified
INJECTION	INJECTION	7489/22T	PASTEUR.	Diphtheria Toxoid Drug Substance
TETRAXIM	TETRAXIM			~
SUSPENSI	SUSPENSI			
ON FOR	ON FOR			
INJECTION	INJECTION			
IN PRE-	IN PRE-			
			SANOFI	Change in the "Absence of taxin
FILLED	FILLED	2800/227	SANOFI	Change in the "Absence of toxin
SYRINGE	SYRINGE	2800/23T	PASTEUR.	(specific toxicity) and
PENTAXIM	PENTAXIM			
POWDER	POWDER			
AND	AND			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR			
SUSPENSI	SUSPENSI			irreversibility of toxoid" Test, i.e.,
ON FOR	ON FOR		SANOFI	removal of the "irreversibility of toxoid"
INJECTION	INJECTION	2801/23T	PASTEUR.	part of the
PENTAXIM	PENTAXIM			
POWDER	POWDER			
AND	AND			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR			
SUSPENSI	SUSPENSI			test, with consequential change in the
ON FOR	ON FOR		SANOFI	acceptance criteria, in line with the
INJECTION	INJECTION	7520/22T, 7521/22T	PASTEUR.	updated
TETRAXIM	TETRAXIM			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR			
INJECTION	INJECTION			
IN PRE-	IN PRE-			
	FILLED		SANOFI	
			PASTEUR.	Ph. Eur. product monograph 0452
FILLED SYRINGE	SYRINGE	7518/22T, 7519/22T		

AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOO D UNITS	AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOO D 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/I NJECTION 200MG/VIA L	TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/I NJECTION 200MG/VIA L	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/I NJECTION 400MG/VIA L	TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/I NJECTION 400MG/VIA L	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	GLAXOSMITH KLINE 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)
PANTOPRA ZOLE ACCORD POWDER FOR SOLUTION FOR INJECTION 40MG/VIAL	PANTOPRA ZOLE 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 evening the mentioned in
				reagent or excipient (when mentioned in the dossier)*
CISPLATIN CONCENT RATE FOR SOLUTION FOR INFUSION 1MG/ML	CISPLATIN CONCENT RATE 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/0.0 25G)G	EPIDUO GEL (0.001G/0.0 25G)G	6170/23T, 7726/23T	GALDERMA INTERNATION AL,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 INTERNATION AL,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 -
REMABIRA T TABLET, FILM COATED 1000MG	REMABIRA T 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/10M G	CHOLZET CAPSULE, HARD 20MG/10M G	9335/22T, 9336/22T, 9337/22T	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 - 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) 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/10M G	CHOLZET CAPSULE, HARD 10MG/10M G	9338/22T, 9339/22T, 9340/22T	EGIS PHARMACEU TICALS 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,

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			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/10M G	CHOLZET CAPSULE, HARD 40MG/10M G	9332/22T, 9333/22T, 9334/22T	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 - 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/10M G	CHOLZET CAPSULE, HARD 20MG/10M G	3102/23T, 3103/23T, 3104/23T, 3105/23T	EGIS PHARMACEU TICALS 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/10M G	CHOLZET CAPSULE, HARD 10MG/10M G	3106/23T, 3107/23T, 3108/23T, 3109/23T	EGIS PHARMACEU TICALS 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 -

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				HUMAN AND VETERINARY 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 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
CHOLZET CAPSULE, HARD 40MG/10M G	CHOLZET CAPSULE, HARD 40MG/10M G	3098/23T, 3099/23T, 3100/23T, 3101/23T	EGIS PHARMACEU TICALS PRIVATE LIMITED COMPANY (EGIS GYÓGYSZER GYÁR ZRT)	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
CIFLOXACI N EAR DROPS SOLUTION 3MG/ML	CIFLOXACI N 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
CREAM 2%	CREAM 2%	9958/231, 9959/231	HELLAS ABEE	
LINEZID SOLUTION FOR INFUSION 2MG/ML	LINEZID SOLUTION FOR INFUSION 2MG/ML	9838/23T	SAPIENS PHARMACEU TICALS 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
CONCERT A TABLET, PROLONG ED- RELEASE 18MG	CONCERT A TABLET, PROLONG ED- RELEASE 18MG	7982/23T, 7983/23T, 7984/23T	JANSSEN- CILAG INTERNATION AL 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
CONCERT A TABLET, PROLONG ED- RELEASE 36MG	CONCERT A TABLET, PROLONG ED- RELEASE 36MG	7979/23T, 7980/23T, 7981/23T	JANSSEN- CILAG INTERNATION AL 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
CONCERT A TABLET, PROLONG ED- RELEASE 54MG	CONCERT A TABLET, PROLONG ED- RELEASE 54MG	7976/23T, 7977/23T, 7978/23T	JANSSEN- CILAG INTERNATION AL 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

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				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
				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,
CONCERT	CONCERT			including the risk management plan -
A TABLET, PROLONG	A TABLET, PROLONG		JANSSEN-	Implementation of change(s) which require to be further substantiated by
ED-	ED-		CILAG	new additional data to be submitted by
RELEASE 36MG	RELEASE 36MG	157/23T	INTERNATION AL NV	the MAH where significant assessment by the competent authority is required*
				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,
CONCERT A TABLET,	CONCERT A TABLET,			including the risk management plan - Implementation of change(s) which
PROLONG	PROLONG		JANSSEN-	require to be further substantiated by
ED- RELEASE	ED- RELEASE		CILAG INTERNATION	new additional data to be submitted by the MAH where significant assessment
18MG	18MG	158/23T	AL NV	by the competent authority is required*
				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
CONCERT	CONCERT			conditions of a marketing authorisation, including the risk management plan -
A TABLET,	A TABLET,			Implementation of change(s) which
PROLONG	PROLONG		JANSSEN-	require to be further substantiated by
ED- RELEASE	ED- RELEASE		CILAG INTERNATION	new additional data to be submitted by the MAH where significant assessment
54MG	54MG	156/23T	AL NV	by the competent authority is required*
VITIS VINIFERA	VITIS VINIFERA		OPELLA HEALTHCARE	
STADA	STADA		GREECE	
TABLET, FILM	TABLET, FILM		SINGLE MEMBER LTD	
COATED	COATED	0444/007	(OPELLA	A.z A.z - ADMINISTRATIVE
360MG	360MG	8441/23T	E.P.E.)	CHANGES - 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
MEDOTRA	MEDOTRA			Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
MOL	MOL			medicinal products following
TABLET, FILM	TABLET, FILM			assessment of the same change for the reference product - Implementation of
COATED	COATED			change(s) for which no new additional
37.5MG/325 MG	37.5MG/325 MG	10039/23T	MEDOCHEMIE LTD	data is required to be submitted by the MAH
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TAZOREX POWDER FOR SOLUTION FOR INJECTION (4G/0.5G)/V IAL	TAZOREX POWDER FOR SOLUTION FOR INJECTION (4G/0.5G)/V IAL	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)/V IAL	TAZOREX POWDER FOR SOLUTION FOR INJECTION (4G/0.5G)/V IAL	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
MICAFUNG IN/PHARM AZAC POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 100MG	MICAFUNG IN/PHARM AZAC POWDER FOR CONCENT RATE 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)
MICAFUNG IN/PHARM AZAC POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 50MG	MICAFUNG IN/PHARM AZAC POWDER FOR CONCENT RATE 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/3M G	YASMIN TABLET, FILM COATED 0.03MG/3M G	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

YASMINEL	YASMINEL			
LE				
TABLET,	TABLET,			
FILM	FILM			A.1 A.1 - ADMINISTRATIVE
COATED	COATED			CHANGES - Change in the name
0.02MG/3M	0.02MG/3M	0000/007	BAYER	and/or address of the marketing
G	G	2286/23T	HELLAS ABEE	authorisation holder
AVELOX	AVELOX			
SOLUTION	SOLUTION			
FOR	FOR			A.1 A.1 - ADMINISTRATIVE
INFUSION	INFUSION			CHANGES - Change in the name
400MG/250	400MG/250		BAYER	and/or address of the marketing
ML	ML	2290/23T	HELLAS ABEE	authorisation holder
GADOVIST	GADOVIST			
PFS	PFS			
SOLUTION	SOLUTION			
FOR	FOR			
INJECTION	INJECTION			
IN	IN			A.1 A.1 - ADMINISTRATIVE
PREFILLED	PREFILLED			CHANGES - Change in the name
SYRINGE	SYRINGE		BAYER	and/or address of the marketing
1MMOL/ML	1MMOL/ML	2292/23T	HELLAS ABEE	authorisation holder
GADOVIST	GADOVIST			
SOLUTION	SOLUTION			A.1 A.1 - ADMINISTRATIVE
FOR	FOR			CHANGES - Change in the name
INJECTION	INJECTION		BAYER	and/or address of the marketing
1MMOL/ML	1MMOL/ML	2293/23T	HELLAS ABEE	authorisation holder
ASPIRIN	ASPIRIN			
EXPRESS	EXPRESS			A.1 A.1 - ADMINISTRATIVE
TABLET,	TABLET,			CHANGES - Change in the name
COATED	COATED		BAYER	and/or address of the marketing
500MG	500MG	2282/23T	HELLAS ABEE	authorisation holder
QLAIRA	QLAIRA			A.1 A.1 - ADMINISTRATIVE
TABLET,	TABLET,			CHANGES - Change in the name
FILM	FILM		BAYER	and/or address of the marketing
COATED	COATED	2285/23T	HELLAS ABEE	authorisation holder
GYNO-	GYNO-			
CANESTEN	CANESTEN			
VAGINAL	VAGINAL			A.1 A.1 - ADMINISTRATIVE
CAPSULE,	CAPSULE,			CHANGES - Change in the name
SOFT	SOFT		BAYER	and/or address of the marketing
500MG	500MG	2283/23T	HELLAS ABEE	authorisation holder
PRIMOVIST	PRIMOVIST			
SOLUTION	SOLUTION			
FOR	FOR			
INJECTION	INJECTION			
IN	IN			
PREFILLED	PREFILLED			A.1 A.1 - ADMINISTRATIVE
SYRINGE	SYRINGE			CHANGES - Change in the name
0.25MMOL/	0.25MMOL/		BAYER	and/or address of the marketing
ML	ML	2294/23T	HELLAS ABEE	authorisation holder
CLEXANE	CLEXANE			
SOLUTION	SOLUTION			
FOR	FOR			
INJECTION	INJECTION			
IN	IN			
PREFILLED	PREFILLED			A.1 A.1 - ADMINISTRATIVE
SYRINGE	SYRINGE		SANOFI	CHANGES - Change in the name
40MG(4000	40MG(4000		WINTHROP	and/or address of the marketing
IU)/0.4ML	IU)/0.4ML	8545/23T	INDUSTRIE.	authorisation holder
CLEXANE	CLEXANE			
SOLUTION	SOLUTION			
FOR	FOR			
INJECTION	INJECTION			
IN	IN			
PREFILLED	PREFILLED			A.1 A.1 - ADMINISTRATIVE
SYRINGE	SYRINGE		SANOFI	CHANGES - Change in the name
60MG(6000	60MG(6000		WINTHROP	and/or address of the marketing
IU)/0.6ML	IU)/0.6ML	8544/23T	INDUSTRIE.	authorisation holder
10,0000				

CLEXANE	CLEXANE			
SOLUTION	SOLUTION			
FOR INJECTION	FOR INJECTION			
IN	IN			
PREFILLED	PREFILLED			A.1 A.1 - ADMINISTRATIVE
SYRINGE	SYRINGE		SANOFI	CHANGES - Change in the name
20MG(2000	20MG(2000		WINTHROP	and/or address of the marketing
IU)/0.2ML	IU)/0.2ML	8546/23T	INDUSTRIE.	authorisation holder
CLEXANE SOLUTION	CLEXANE			
FOR	SOLUTION FOR			
INJECTION	INJECTION			
IN	IN			
PREFILLED	PREFILLED			A.1 A.1 - ADMINISTRATIVE
SYRINGE	SYRINGE		SANOFI	CHANGES - Change in the name
80MG(8000	80MG(8000		WINTHROP	and/or address of the marketing
IU)/0.8ML GEMCITABI	IU)/0.8ML GEMCITABI	8543/23T	INDUSTRIE.	authorisation holder A.5.b A.5.b - ADMINISTRATIVE
NE	NE			CHANGES - Change in the name
ACCORD	ACCORD			and/or address of a
CONCENT	CONCENT			manufacturer/importer of the finished
RATE FOR	RATE FOR			product (including batch release or
SOLUTION	SOLUTION			quality control testing sites) - The
FOR	FOR		ACCORD	activities for which the
INFUSION		5421/22T	HEALTHCARE	manufacturer/importer is responsible do
100MG/ML	100MG/ML	5431/23T	S.L.U	not include batch release B.II.b.1.a B.II.b.1.a - QUALITY
TICAGREL	TICAGREL			CHANGES - FINISHED PRODUCT -
OR/MYLAN	OR/MYLAN			Manufacture - Replacement or addition
TABLET,	TABLET,			of a manufacturing site for part or all of
FILM	FILM		MYLAN	the manufacturing process of the
COATED	COATED		IRELAND	finished product - Secondary packaging
90MG	90MG	5005/23T	LIMITED	site B.II.b.1.a B.II.b.1.a - QUALITY
TICAGREL	TICAGREL			CHANGES - FINISHED PRODUCT -
OR/MYLAN	OR/MYLAN			Manufacture - Replacement or addition
TABLET,	TABLET,			of a manufacturing site for part or all of
FILM	FILM		MYLAN	the manufacturing process of the
COATED	COATED		IRELAND	finished product - Secondary packaging
60MG CABAZITA	60MG CABAZITA	5006/23T	LIMITED	site
XEL	XEL			A.5.b A.5.b - ADMINISTRATIVE
FRESENIU	FRESENIU			CHANGES - Change in the name
S KABI	S KABI			and/or address of a
CONCENT	CONCENT			manufacturer/importer of the finished
RATE FOR	RATE FOR			product (including batch release or
SOLUTION	SOLUTION			
			FRESENIUS	quality control testing sites) - The
FOR	FOR		KABI HELLAS	activities for which the
INFUSION	FOR INFUSION	5093/23T	KABI HELLAS SINGLE	activities for which the manufacturer/importer is responsible do
	FOR	5093/23T	KABI HELLAS	activities for which the
INFUSION	FOR INFUSION	5093/23T	KABI HELLAS SINGLE	activities for which the manufacturer/importer is responsible do not include batch release C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
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THYROFIX TABLET 175MCG	THYROFIX TABLET 175MCG	8767/23T, 8768/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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 PHARMACEU TICAL LABORATORI ES 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
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- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European PHARMACEU THYROFIX TABLET 125MCG- Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European PHARMACEU TICAL LABORATORI 125MCGTHYROFIX THYROFIX THYROFIX THYROFIX THYROFIX THYROFIX TABLET8773/23T, 8774/23TES SA ES SA approved manufacturerTHYROFIX THYROFIX TABLETTHYROFIX THYROFIX TABLETUNI-PHARMA KLEONB.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS					
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	100MCG	100MCG	8777/23T, 8778/23T	TSETIS	- Submission of a new or updated Ph.

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			PHARMACEU TICAL LABORATORI ES 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 B.III.1.a.2 B.III.1.a.2 - QUALITY
THYROFIX TABLET 137MCG	THYROFIX TABLET 137MCG	8771/23T, 8772/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES SA	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 PHARMACEU TICAL LABORATORI ES 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 DECANOA S INJECTION 50MG/1ML	HALDOL DECANOA S INJECTION 50MG/1ML	8212/23T	JANSSEN- CILAG INTERNATION AL NV	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
HALDOL DECANOA S INJECTION	HALDOL DECANOA S INJECTION	9211/22T	JANSSEN- CILAG INTERNATION AL NV	A.z A.z - ADMINISTRATIVE
100MG/1ML CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	100MG/1ML CIFOBAN SOLUTION FOR INFUSION 136MMOL/L	8211/23T 5021/23T	FRESENIUS MEDICAL CARE DEUTSCHLAN D GMBH	CHANGES - Other variation 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	CIFOBAN SOLUTION FOR INFUSION 136MMOL/L CIFOBAN	4954/23T	FRESENIUS MEDICAL CARE DEUTSCHLAN D GMBH FRESENIUS	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
SOLUTION FOR INFUSION 136MMOL/L	SOLUTION FOR INFUSION 136MMOL/L	5022/23T	MEDICAL CARE DEUTSCHLAN D GMBH	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products C.I.z C.I.z - SAFETY, EFFICACY,
CIFOBAN SOLUTION FOR INFUSION 136MMOL/L DICETEL	CIFOBAN SOLUTION FOR INFUSION 136MMOL/L DICETEL	4969/23T	FRESENIUS MEDICAL CARE DEUTSCHLAN D GMBH VIATRIS	C.I.Z C.I.Z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TABLET, FILM	TABLET, FILM	1412/23T	HEALTHCARE LIMITED.	B.I.z B.I.z - Quality change - Active substance - Other variation

COATED	COATED			
50MG	50MG			
GENEMEN T TABLET, FILM COATED 20MG	GENEMEN T TABLET, FILM COATED 20MG	8560/23T	SAPIENS PHARMACEU TICALS 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
GENEMEN T TABLET, FILM COATED 5MG	GENEMEN T TABLET, FILM COATED 5MG	8561/23T	SAPIENS PHARMACEU TICALS 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 APTAPHAR MA POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	CEFEPIME APTAPHAR MA POWDER FOR SOLUTION FOR INJECTION /INFUSION 1G	8971/23T	APTA MEDICA INTERNACION AL 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 APTAPHAR MA POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G	CEFEPIME APTAPHAR MA POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G	8970/23T	APTA MEDICA INTERNACION AL 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
EPLERENO NE ACCORD TABLET, FILM COATED 25MG	EPLERENO NE 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

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

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				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, SUBLINGU AL 2MG	SUBUTEX TABLET, SUBLINGU AL 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, SUBLINGU AL 8MG	SUBUTEX TABLET, SUBLINGU AL 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	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 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
CLOMIPRA MINE	CLOMIPRA MINE			substance or of an excipient B.II.a.3.z B.II.a.3.z - QUALITY
TABLET,	TABLET,			CHANGES - FINISHED PRODUCT -
FILM	FILM			Description and composition - Changes
COATED	COATED	9496/23T, 9497/23T,	REMEDICA	in the composition (excipients) of the
25MG	25MG	9498/23T	LTD	finished product - Other changes C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
INJEXATE	INJEXATE			Leaflet of human medicinal products
SOLUTION	SOLUTION			intended to implement the outcome of a
FOR INJECTION	FOR INJECTION			procedure concerning PSUR or PASS, or the outcome of the assessment done
IN	IN			by the competent authority under
PREFILLED	PREFILLED		ACCORD	Articles 45 or 46 of Regulation
SYRINGE 50MG/ML	SYRINGE 50MG/ML	4711/23T	HEALTHCARE S.L.U	1901/2006 - Implementation of wording agreed by the competent authority
JOINIG/IVIL	JOINIG/IVIL	4711/231	0.L.0	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
REXANIB				Stability - Change in the shelf-life or
TABLET, FILM	TABLET, FILM			storage conditions of the finished product - Extension of the shelf life of
COATED	COATED		REMEDICA	the finished product - As packaged for
200MG	200MG	6331/23T	LTD	sale (supported by real time data)
TAMSULOS	TAMSULOS			
AUROBIND	AUROBIND			
O TABLET,	O TABLET,			
PROLONG ED-	PROLONG ED-		AUROBINDO PHARMA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented)
RELEASE	RELEASE		(MALTA)	name of the medicinal product - for
0.4MG	0.4MG	6893/23T	LIMITED	Nationally Authorised Products
PALIPERID ONE/TEVA	PALIPERID ONE/TEVA			B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY
PHARMA	PHARMA			CHANGES - FINISHED PRODUCT -
PROLONG	PROLONG			Manufacture - Change to importer,
	ED			batch release arrangements and quality control testing of the finished product -
RELEASE SUSPENSI	RELEASE SUSPENSI			Replacement or addition of a
ON FOR	ON FOR			manufacturer responsible for
INJECTION	INJECTION	6404/22T		importation and/or batch release - Not
75MG	75MG	6404/23T	PHARMA BV	including batch control/testing

PALIPERID	PALIPERID			
ONE/TEVA	ONE/TEVA			B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY
PHARMA	PHARMA			CHANGES - FINISHED PRODUCT -
PROLONG	PROLONG			Manufacture - Change to importer,
ED	ED			batch release arrangements and quality
RELEASE	RELEASE			control testing of the finished product -
SUSPENSI	SUSPENSI			Replacement or addition of a
ON FOR	ON FOR			manufacturer responsible for
INJECTION	INJECTION		TEVA	importation and/or batch release - Not
150MG	150MG	6402/23T	PHARMA BV	including batch control/testing
PALIPERID	PALIPERID			
ONE/TEVA	ONE/TEVA			B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY
PHARMA	PHARMA			CHANGES - FINISHED PRODUCT -
PROLONG	PROLONG			Manufacture - Change to importer,
ED	ED			batch release arrangements and quality
RELEASE	RELEASE			control testing of the finished product -
SUSPENSI	SUSPENSI			Replacement or addition of a
ON FOR	ON FOR			manufacturer responsible for
INJECTION	INJECTION		TEVA	importation and/or batch release - Not
		0.400/00T		
100MG	100MG	6403/23T	PHARMA BV	including batch control/testing
RAPIBLOC	RAPIBLOC			B.II.d.1.c B.II.d.1.c - QUALITY
POWDER	POWDER			CHANGES - FINISHED PRODUCT -
FOR	FOR			Control of finished product - Change in
-	-			
SOLUTION	SOLUTION			the specification parameters and/or
FOR	FOR			limits of the finished product - Addition
INFUSION	INFUSION		AMOMED	of a new specification parameter to the
			-	
300MG/VIA	300MG/VIA		PHARMA	specification with its corresponding test
L	L	8381/23T	GMBH.	method
PIPERACIL	PIPERACIL			B.III.1.a.2 B.III.1.a.2 - QUALITY
LIN +	LIN +			CHANGES - CEP/TSE/MONOGRAPHS
TAZOBACT	TAZOBACT			- Submission of a new or updated Ph.
AM/GENER	AM/GENER			Eur. Certificate of suitability or deletion
ICS	ICS			of Ph. Eur. certificate of suitability: For
POWDER	POWDER			an active substance For a starting
FOR	FOR			material/reagent/intermediate used in
SOLUTION	SOLUTION			the manufacturing process of the active
FOR	FOR			substance For an excipient - European
-	-			
INJECTION	INJECTION			Pharmacopoeial Certificate of Suitability
/INFUSION	/INFUSION		MYLAN	to the relevant Ph. Eur. Monograph -
(2G/0.25G)/	(2G/0.25G)/		IRELAND	Updated certificate from an already
VIAL	VIAL	9054/23T	LIMITED	approved manufacturer
		9034/231		
PIPERACIL	PIPERACIL			B.III.1.a.2 B.III.1.a.2 - QUALITY
LIN +	LIN +			CHANGES - CEP/TSE/MONOGRAPHS
TAZOBACT	TAZOBACT			- Submission of a new or updated Ph.
AM/GENER	AM/GENER			Eur. Certificate of suitability or deletion
ICS	ICS			of Ph. Eur. certificate of suitability: For
POWDER	POWDER			an active substance For a starting
FOR	FOR			material/reagent/intermediate used in
SOLUTION	SOLUTION			the manufacturing process of the active
FOR	FOR			substance For an excipient - European
INJECTION	INJECTION			Pharmacopoeial Certificate of Suitability
/INFUSION	/INFUSION		MYLAN	to the relevant Ph. Eur. Monograph -
(4G/0.5G)/V	(4G/0.5G)/V		IRELAND	Updated certificate from an already
IAL	IAL	9053/23T	LIMITED	approved manufacturer
				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
IMODIUM	IMODIUM		JOHNSON &	control testing of the finished product -
PLUS	PLUS		JOHNSON	Replacement or addition of a
TABLET	TABLET		HELLAS	manufacturer responsible for
2MG/125M	2MG/125M		CONSUMER	importation and/or batch release - Not
G	G	8176/23T	AE	including batch control/testing
<u> </u>	l Ŭ		, <u>,</u>	
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
	CANDESA			Eur. Certificate of suitability or deletion
			1	
CANDESA				
RTAN TAD	RTAN TAD			of Ph. Eur. certificate of suitability: For
			TAD PHARMA	of Ph. Eur. certificate of suitability: For an active substance For a starting
RTAN TAD	RTAN TAD	8946/23T	TAD PHARMA GMBH	

				the manufacturing process of 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.2 B.III.1.a.2 - QUALITY
CANDESA RTAN TAD TABLET 32MG	CANDESA RTAN TAD TABLET 32MG	8945/23T	TAD PHARMA GMBH	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.b.1.b B.I.b.1.b - QUALITY
FENIVIR TINTED CREAM 1%	FENIVIR TINTED CREAM 1%	1246/23T, 1247/23T, 1248/23T, 1247/23T, 1248/23T, 1249/23T, 1250/23T, 1251/23T, 1252/23T, 1253/23T, 1256/23T, 1255/23T, 1256/23T, 1259/23T, 1260/23T, 1263/23T, 1262/23T, 1265/23T, 1266/23T, 1267/23T, 1268/23T, 1269/23T	OMEGA PHARMA HELLAS S.A	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 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 manufacture of a starting material/reagent/intermediat C.I.z C.I.z - SAFETY, EFFICACY,
LIPOFOR CAPSULE, HARD 300MG	LIPOFOR CAPSULE, HARD 300MG	8887/23T	REMEDICA LTD	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 CONCENT RATE FOR SOLUTION	REFENTA POWDER FOR CONCENT RATE FOR SOLUTION	9949/23T	SAPIENS PHARMACEU TICALS 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	FOR			
INJECTION OR	INJECTION OR			
INFUSION	INFUSION			
2MG	2MG			
REFENTA	REFENTA			
POWDER FOR	POWDER FOR			
CONCENT	CONCENT			
RATE FOR	RATE FOR			
SOLUTION	SOLUTION			B.II.e.7.b B.II.e.7.b - QUALITY
FOR INJECTION	FOR INJECTION			CHANGES - FINISHED PRODUCT - Container closure system - Change in
OR	OR		SAPIENS	supplier of packaging components or
INFUSION	INFUSION		PHARMACEU	devices (when mentioned in the dossier)
1MG	1MG	9950/23T	TICALS LTD	- Replacement or addition of a supplier
				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 -
PRODUOD	PRODUOD			HUMAN AND VETERINARY
OPA	OPA			MEDICINAL PRODUCTS - Submission
SOLUTION FOR	SOLUTION FOR			of results of assessments carried out on target patient groups in order to comply
INFUSION	INFUSION	2153/23T, 2154/23T,	ABBVIE	with Article 59(3) of Directive
(240MG+12	(240MG+12	2155/23T, 2156/23T,	PHARMACEU	2001/83/EC and any resulting change to
MG)/ML	MG)/ML	2157/23T	TICALS S.A.	the Package Leaflet
BINOSTO	BINOSTO			B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT -
EFFERVES	EFFERVES			Manufacture - Change to in-process
CENT	CENT			tests or limits applied during the
TABLET	TABLET	0202/02T		manufacture of the finished product -
70MG	70MG	8323/23T	GALENICA SA	Other changes 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
ADAGREL	ADAGREL			of a summary of pharmacovigilance
TABLET, FILM	TABLET, FILM		SAPIENS	system, changes in QPPV (including contact details) and/or changes in the
COATED	COATED		PHARMACEU	Pharmacovigilance System Master File
75MG	75MG	8555/23T	TICALS LTD	(PSMF) location
PRISMASO	PRISMASO			B.III.1.a.2 B.III.1.a.2 - QUALITY
L POTASSIU	L POTASSIU			CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
M	M			Eur. Certificate of suitability or deletion
SOLUTION	SOLUTION		BAXTER	of Ph. Eur. certificate of suitability: For
FOR	FOR	7965/23T	HOLDING B.V.	an active substance For a starting

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HAEMOFIL TRATION	HAEMOFIL TRATION			material/reagent/intermediate used in the manufacturing process of the active
AND	AND			substance For an excipient - European
HAEMODIA	HAEMODIA			Pharmacopoeial Certificate of Suitability
LYSIS	LYSIS			to the relevant Ph. Eur. Monograph -
2MMOL/L	2MMOL/L			Updated certificate from an already
				approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
PRISMASO	PRISMASO			CHANGES - CEP/TSE/MONOGRAPHS
L	L			- Submission of a new or updated Ph.
POTASSIU	POTASSIU			Eur. Certificate of suitability or deletion
M	M			of Ph. Eur. certificate of suitability: For
SOLUTION FOR	SOLUTION FOR			an active substance For a starting material/reagent/intermediate used in
HAEMOFIL	HAEMOFIL			the manufacturing process of the active
TRATION	TRATION			substance For an excipient - European
AND	AND			Pharmacopoeial Certificate of Suitability
HAEMODIA	HAEMODIA			to the relevant Ph. Eur. Monograph -
LYSIS	LYSIS		BAXTER	Updated certificate from an already
4MMOL/L	4MMOL/L	7964/23T	HOLDING B.V.	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
NE KABI SOLUTION	NE KABI SOLUTION			conditions of the active substance where no Ph. Eur. Certificate of
FOR	FOR		FRESENIUS	Suitability covering the retest period is
INJECTION	INJECTION		KABI HELLAS	part of the approved dossier - Re-test
5MG/ML	5MG/ML	8005/23T	A.E.	period/storage period -
		0000/201	7.121	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
				Stability - Change in the re-test
ROPIVACAI	ROPIVACAI			period/storage period or storage
NE KABI	NE KABI			conditions of the active substance
SOLUTION	SOLUTION			where no Ph. Eur. Certificate of
FOR	FOR		FRESENIUS	Suitability covering the retest period is
INFUSION 2MG/ML	INFUSION 2MG/ML	8006/23T	KABI HELLAS A.E.	part of the approved dossier - Re-test period/storage period -
21010/1012	21010/1012	0000/231	Λ.Ε.	B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
				Stability - Change in the re-test
ROPIVACAI	ROPIVACAI			period/storage period or storage
NE KABI	NE KABI			conditions of the active substance
SOLUTION	SOLUTION			where no Ph. Eur. Certificate of
FOR	FOR		FRESENIUS	Suitability covering the retest period is
INJECTION	INJECTION	0007/00T	KABI HELLAS	part of the approved dossier - Re-test
2MG/ML	2MG/ML	8007/23T	A.E.	period/storage period -
				B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE -
				Stability - Change in the re-test
ROPIVACAI	ROPIVACAI			period/storage period or storage
NE KABI	NE KABI			conditions of the active substance
SOLUTION	SOLUTION			where no Ph. Eur. Certificate of
FOR	FOR		FRESENIUS	Suitability covering the retest period is
INJECTION	INJECTION		KABI HELLAS	part of the approved dossier - Re-test
7.5MG/ML	7.5MG/ML	8004/23T	A.E.	period/storage period -
				B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
ROPIVACAI	ROPIVACAI			Stability - Change in the re-test period/storage period or storage
NE KABI	NE KABI			conditions of the active substance
SOLUTION	SOLUTION			where no Ph. Eur. Certificate of
FOR	FOR		FRESENIUS	Suitability covering the retest period is
INJECTION	INJECTION		KABI HELLAS	part of the approved dossier - Re-test
10MG/ML	10MG/ML	8003/23T	A.E.	period/storage period -
NEURONTI	NEURONTI			A.4 A.4 - ADMINISTRATIVE
N	N			CHANGES - Change in the name
CAPSULE,	CAPSULE,			and/or address of: a manufacturer
HARD	HARD	9120/22T 0121/22T		(including where relevant quality control
300MG	300MG	8130/23T, 8131/23T	HELLAS LTD	testing sites); or an ASMF holder; or a

	1			a compliant of the active such as the second
				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
				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
ZOLOFT	ZOLOFT			manufacturer/importer of the finished product (including batch release or
TABLET, FILM	TABLET, FILM			quality control testing sites) - The activities for which the
COATED	COATED		VIATRIS	manufacturer/importer is responsible do
100MG	100MG	8146/23T, 8147/23T	HELLAS LTD	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)
				A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
				and/or address of a manufacturer/importer of the finished
CELEBREX	CELEBREX			product (including batch release or quality control testing sites) - The
CAPSULE,	CAPSULE,			activities for which the
HARD 200MG	HARD 200MG	8150/23T, 8151/23T	VIATRIS HELLAS LTD	manufacturer/importer is responsible do not include batch release
				A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name
CELEBREX CAPSULE,	CELEBREX CAPSULE,			and/or address of: a manufacturer (including where relevant quality control
HARD	HARD		VIATRIS	testing sites); or an ASMF holder; or a
200MG	200MG	8150/23T, 8151/23T	HELLAS LTD	supplier of the active substance, starting

				material reagent or intermediate used
				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
				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
DETRUSIT OL	DETRUSIT OL			manufacturer/importer of the finished
TABLET,	TABLET,			product (including batch release or quality control testing sites) - The
FILM	FILM			activities for which the
COATED 2MG	COATED 2MG	8122/23T, 8123/23T	VIATRIS HELLAS LTD	manufacturer/importer is responsible do not include batch release
200	200			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
ZARATOR	ZARATOR			product (including batch release or
TABLET, FILM	TABLET, FILM			quality control testing sites) - The activities for which the
COATED	COATED		VIATRIS	manufacturer/importer is responsible do
10MG	10MG	8138/23T, 8139/23T	HELLAS LTD	not include batch release A.4 A.4 - ADMINISTRATIVE
				CHANGES - Change in the name
LIPITOR TABLET,	LIPITOR TABLET,			and/or address of: a manufacturer (including where relevant quality control
FILM	FILM			testing sites); or an ASMF holder; or a
COATED	COATED	0440/00T 0444/00T		supplier of the active substance, starting
10MG	10MG	8140/23T, 8141/23T	HELLAS LTD	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	LIPITOR TABLET, FILM COATED		VIATRIS	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
20MG	20MG	8142/23T, 8143/23T	HELLAS LTD	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
				A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name
NEURONTI N CAPSULE, HARD 400MG	NEURONTI N CAPSULE, HARD 400MG	8128/23T, 8129/23T	VIATRIS HELLAS LTD	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

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				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
				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
ZOLOFT	ZOLOFT			manufacturer/importer of the finished product (including batch release or
TABLET,	TABLET,			quality control testing sites) - The
FILM	FILM			activities for which the
COATED	COATED		VIATRIS	manufacturer/importer is responsible do
50MG	50MG	8148/23T, 8149/23T	HELLAS LTD	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)
				A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
				and/or address of a manufacturer/importer of the finished
XALATAN	XALATAN			product (including batch release or
EYE	EYE			quality control testing sites) - The
DROPS,	DROPS,			activities for which the
SOLUTION	SOLUTION		VIATRIS	manufacturer/importer is responsible do
50MCG/ML	50MCG/ML	8132/23T, 8133/23T	HELLAS LTD	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
CELEBREX	CELEBREX			supplier of the active substance, starting
CAPSULE,	CAPSULE,			material, reagent or intermediate used
HARD	HARD 100MG	0450/00T 0450/00T	VIATRIS	in the manufacture of the active substance (where specified in the
100MG		8152/23T, 8153/23T	HELLAS LTD	SUBSTANCA UNDARA SDACITIAA IN TAA

	I		1	technical decoirs) where is a Dh. Eve
				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 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
CELEBREX	CELEBREX			quality control testing sites) - The
CAPSULE,	CAPSULE,		VIATRIS	activities for which the
HARD 100MG	HARD 100MG	8152/23T, 8153/23T	HELLAS LTD	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) A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
				and/or address of a manufacturer/importer of the finished
LIPITOR	LIPITOR			product (including batch release or
TABLET, FILM	TABLET, FILM			quality control testing sites) - The activities for which the
COATED	COATED		VIATRIS	manufacturer/importer is responsible do
40MG	40MG	8144/23T, 8145/23T	HELLAS LTD	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
INSPRA				supplier of the active substance, starting
TABLET, FILM	TABLET, FILM			material, reagent or intermediate used in the manufacture of the active
COATED 50MG	COATED 50MG	8124/23T, 8125/23T	VIATRIS HELLAS LTD	substance (where specified in the technical dossier) where no Ph. Eur.

				1
				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
				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
ZARATOR	ZARATOR			product (including batch release or
TABLET,	TABLET,			quality control testing sites) - The
FILM	FILM			activities for which the
COATED	COATED		VIATRIS	manufacturer/importer is responsible do
20MG	20MG	8136/23T, 8137/23T	HELLAS LTD	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
				Loubotones (where encoified in the
				substance (where specified in the
				technical dossier) where no Ph. Eur.
				technical dossier) where no Ph. Eur. Certificate of Suitability is part of the
				technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of
				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) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of
				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)
				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
				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
ZARATOR	ZARATOR			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
TABLET,	TABLET,			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
TABLET, FILM	TABLET, FILM			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
TABLET, FILM COATED	TABLET, FILM COATED	9424/02T 0425/02T	VIATRIS	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
TABLET, FILM COATED 40MG	TABLET, FILM COATED 40MG	8134/23T, 8135/23T	VIATRIS HELLAS LTD	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
TABLET, FILM COATED 40MG CELEBREX	TABLET, FILM COATED 40MG CELEBREX	8134/23T, 8135/23T	-	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 A.1 A.1 - ADMINISTRATIVE
TABLET, FILM COATED 40MG CELEBREX CAPSULE,	TABLET, FILM COATED 40MG CELEBREX CAPSULE,	8134/23T, 8135/23T	HELLAS LTD	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 A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD	TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD		HELLAS LTD	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 A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
TABLET, FILM COATED 40MG CELEBREX CAPSULE,	TABLET, FILM COATED 40MG CELEBREX CAPSULE,	8134/23T, 8135/23T 4155/23T	HELLAS LTD	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 A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD 200MG	TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD 200MG		HELLAS LTD	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 A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD 200MG NORVASC CAPSULE, HARD	TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD 200MG NORVASC CAPSULE, HARD	4155/23T	HELLAS LTD VIATRIS HELLAS LTD VIATRIS	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 A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD 200MG NORVASC CAPSULE, HARD 10MG	TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD 200MG NORVASC CAPSULE, HARD 10MG		HELLAS LTD VIATRIS HELLAS LTD	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 A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD 200MG NORVASC CAPSULE, HARD 10MG EFEXOR	TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD 200MG NORVASC CAPSULE, HARD 10MG EFEXOR	4155/23T	HELLAS LTD VIATRIS HELLAS LTD VIATRIS HELLAS LTD	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 A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD 200MG NORVASC CAPSULE, HARD 10MG	TABLET, FILM COATED 40MG CELEBREX CAPSULE, HARD 200MG NORVASC CAPSULE, HARD 10MG	4155/23T	HELLAS LTD VIATRIS HELLAS LTD VIATRIS	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 A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

ED ED RELEASE and/or address of the marketing authorisation holder 37.5MG 37.5MG	RELEASE CAPSULES 37.5MG LIPITOR TABLET, CHEWABL E 5MG LIPITOR TABLET, CHEWABL E 20MG CELEBREX CAPSULE, HARD 100MG NEURONTI N CAPSULE, HARD 300MG	RELEASE CAPSULES 37.5MG LIPITOR TABLET, CHEWABL E 5MG LIPITOR TABLET, CHEWABL E 20MG CELEBREX CAPSULE, HARD 100MG NEURONTI N CAPSULE, HARD 300MG XALATAN EYE DROPS, SOLUTION 50MCG/ML	4172/23T 4156/23T	VIATRIS HELLAS LTD VIATRIS HELLAS LTD VIATRIS	authorisation holderA.1 A.1 - ADMINISTRATIVECHANGES - Change in the nameand/or address of the marketingauthorisation holderA.1 A.1 - ADMINISTRATIVECHANGES - Change in the nameand/or address of the marketingauthorisation holderA.1 A.1 - ADMINISTRATIVECHANGES - Change in the nameand/or address of the marketingauthorisation holderA.1 A.1 - ADMINISTRATIVECHANGES - Change in the nameand/or address of the marketingauthorisation holderA.1 A.1 - ADMINISTRATIVECHANGES - Change in the nameand/or address of the marketing
CAPSULES A:1 A:1 - ADMINISTRATIVE LIPITOR LIPITOR TABLET, VIATRIS CHEWABL CHEWABL ESMG 4174/23T HELLS LTD A:1 A:1 - ADMINISTRATIVE CHEWABL CHEWABL ESMG 4174/23T HELLS LTD A:1 A:1 - ADMINISTRATIVE CHEWABL CHEWABL CHEWABL CHEWABL CHEWABL CHEWABL CHEWABL VIATRIS and/or address of the marketing and/or address of the marketing <tr< td=""><td>CAPSULES 37.5MG LIPITOR TABLET, CHEWABL E 5MG LIPITOR TABLET, CHEWABL E 20MG CELEBREX CAPSULE, HARD 100MG NEURONTI N CAPSULE, HARD 300MG</td><td>CAPSULES 37.5MG LIPITOR TABLET, CHEWABL E 5MG LIPITOR TABLET, CHEWABL E 20MG CELEBREX CAPSULE, HARD 100MG NEURONTI N CAPSULE, HARD 300MG XALATAN EYE DROPS, SOLUTION 50MCG/ML</td><td>4172/23T 4156/23T</td><td>VIATRIS HELLAS LTD VIATRIS HELLAS LTD VIATRIS</td><td>A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing</td></tr<>	CAPSULES 37.5MG LIPITOR TABLET, CHEWABL E 5MG LIPITOR TABLET, CHEWABL E 20MG CELEBREX CAPSULE, HARD 100MG NEURONTI N CAPSULE, HARD 300MG	CAPSULES 37.5MG LIPITOR TABLET, CHEWABL E 5MG LIPITOR TABLET, CHEWABL E 20MG CELEBREX CAPSULE, HARD 100MG NEURONTI N CAPSULE, HARD 300MG XALATAN EYE DROPS, SOLUTION 50MCG/ML	4172/23T 4156/23T	VIATRIS HELLAS LTD VIATRIS HELLAS LTD VIATRIS	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
37.5MG 37.5MG A1 A.1 - ADMINISTRATIVE LIPITOR A.1 A.1 - ADMINISTRATIVE CHEWABL VIATRIS authorisation holder E.6MG E.5MG 4174/23T LIPITOR A.1 A.1 - ADMINISTRATIVE CHEWABL VIATRIS E.6MG E.20MG 4172/23T TABLET TABLET CHANACES - Change in the name and/or address of the marketing authorisation holder CHEWABL CHEWABL VIATRIS E.20MG E.20MG 4172/23T CELEBREX CELEBREX CHANACES - Change in the name and/or address of the marketing authorisation holder NEURONTI N A.1 A.1 -ADMINISTRATIVE CAPSULE, CAPSULE, VIATRIS HARD NALATAN XALATAN YALATAN XALATAN A.1 A.1 ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A	37.5MG LIPITOR TABLET, CHEWABL E 5MG LIPITOR TABLET, CHEWABL E 20MG CELEBREX CAPSULE, HARD 100MG NEURONTI N CAPSULE, HARD 300MG	37.5MG LIPITOR TABLET, CHEWABL E 5MG LIPITOR TABLET, CHEWABL E 20MG CELEBREX CAPSULE, HARD 100MG NEURONTI N CAPSULE, HARD 300MG XALATAN EYE DROPS, SOLUTION 50MCG/ML	4172/23T 4156/23T	VIATRIS HELLAS LTD VIATRIS HELLAS LTD VIATRIS	CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
LIPITOR LIPITOR TABLET, TABLET	LIPITOR TABLET, CHEWABL E 5MG LIPITOR TABLET, CHEWABL E 20MG CELEBREX CAPSULE, HARD 100MG NEURONTI N CAPSULE, HARD 300MG	LIPITOR TABLET, CHEWABL E 5MG LIPITOR TABLET, CHEWABL E 20MG CELEBREX CAPSULE, HARD 100MG NEURONTI N CAPSULE, HARD 300MG XALATAN EYE DROPS, SOLUTION 50MCG/ML	4172/23T 4156/23T	VIATRIS HELLAS LTD VIATRIS HELLAS LTD VIATRIS	CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
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LIPITOR LIPITOR A.1 A.1 - ADMINISTRATIVE			4170/23T	-	
			1110/201		
TABLET, TABLET, CHANGES - Change in the name	TABLET,				CHANGES - Change in the name
				VIATPIC	
	-		4171/00T	-	
E 40MG E 40MG 4171/23T HELLAS LTD authorisation holder			41/1/231	HELLAS LID	
XR XR VIATRIS A.1 A.1 - ADMINISTRATIVE			4405/00T		
I CAPSULE. CAPSULE. 4165/231 HELLASTID. CHANGES - Change in the name	CAPSULE,	CAPSULE,	4165/23T	HELLAS LTD	CHANGES - Change in the name

		•		
HARD,	HARD,			and/or address of the marketing
PROLONG	PROLONG			authorisation holder
ED-	ED-			
RELEASE	RELEASE			
75MG	75MG			
ZOLOFT	ZOLOFT			
TABLET,	TABLET,			A.1 A.1 - ADMINISTRATIVE
FILM	FILM			_
				CHANGES - Change in the name
COATED	COATED	4470/20T	VIATRIS	and/or address of the marketing
50MG	50MG	4179/23T	HELLAS LTD	authorisation holder
NEURONTI	NEURONTI			
Ν	Ν			A.1 A.1 - ADMINISTRATIVE
CAPSULE,	CAPSULE,			CHANGES - Change in the name
HARD	HARD		VIATRIS	and/or address of the marketing
400MG	400MG	4162/23T	HELLAS LTD	authorisation holder
INSPRA	INSPRA			
TABLET,	TABLET,			A.1 A.1 - ADMINISTRATIVE
FILM	FILM			CHANGES - Change in the name
COATED	COATED		VIATRIS	and/or address of the marketing
25MG	25MG	4161/23T	HELLAS LTD	authorisation holder
ZARATOR	ZARATOR	1101/201		
TABLET,	TABLET,			A.1 A.1 - ADMINISTRATIVE
FILM	FILM		1447510	CHANGES - Change in the name
COATED	COATED		VIATRIS	and/or address of the marketing
10MG	10MG	4168/23T	HELLAS LTD	authorisation holder
INSPRA	INSPRA			
TABLET,	TABLET,			A.1 A.1 - ADMINISTRATIVE
FILM	FILM			CHANGES - Change in the name
COATED	COATED		VIATRIS	and/or address of the marketing
50MG	50MG	4160/23T	HELLAS LTD	authorisation holder
LIPITOR	LIPITOR			
TABLET,	TABLET,			A.1 A.1 - ADMINISTRATIVE
				_
FILM	FILM			CHANGES - Change in the name
COATED	COATED	1177 / O O T	VIATRIS	and/or address of the marketing
10MG	10MG	4177/23T	HELLAS LTD	authorisation holder
LIPITOR	LIPITOR			
TABLET,	TABLET,			A.1 A.1 - ADMINISTRATIVE
FILM	FILM			CHANGES - Change in the name
COATED	COATED		VIATRIS	and/or address of the marketing
40MG	40MG	4175/23T	HELLAS LTD	authorisation holder
LIPITOR	LIPITOR			
TABLET,	TABLET,			A.1 A.1 - ADMINISTRATIVE
FILM	FILM			CHANGES - Change in the name
COATED	COATED		VIATRIS	and/or address of the marketing
		4176/22T		0
20MG	20MG	4176/23T	HELLAS LTD	authorisation holder
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of the assessment done
				by the competent authority under
				Articles 45 or 46 of Regulation
				1901/2006 - Implementation of wording
				agreed by the competent authority
				C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
DUODODA	DUODODA			intended to implement the outcome of a
DUODOPA	DUODOPA		ABBVIE	procedure concerning PSUR or PASS,
	IN ITE OTIVI			
INTESTINA L GEL	INTESTINA L GEL	7409/23T	PHARMACEU TICALS S.A.	or the outcome of 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
				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 -
ADIOEDT				Description and composition - Changes
ARICEPT TABLET,	ARICEPT TABLET,			in the composition (excipients) of the finished product - Other excipients - Any
FILM	FILM			minor adjustment of the quantitative
COATED 5MG	COATED 5MG	9893/23T, 9894/23T, 9895/23T, 9896/23T	PFIZER HELLAS AE	composition of the finished product with respect to excipients
				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 -
ARICEPT	ARICEPT			Description and composition - Changes in the composition (excipients) of the
TABLET,	TABLET,			finished product - Other excipients - Any
FILM COATED	FILM COATED	9889/23T, 9890/23T,	PFIZER	minor adjustment of the quantitative composition of the finished product with
10MG	10MG	9891/23T, 9892/23T	HELLAS AE	respect to excipients
				B.II.e.4.c B.II.e.4.c - QUALITY CHANGES - FINISHED PRODUCT -
				Container closure system - Change in
HYDROCO	HYDROCO			shape or dimensions of the container or
RTISONE MEDO	RTISONE MEDO			closure (immediate packaging) - Sterile medicinal products
POWDER	POWDER			B.II.e.6.b B.II.e.6.b - QUALITY
FOR SOLUTION	FOR SOLUTION			CHANGES - FINISHED PRODUCT - Container closure system - Change in
FOR	FOR			any part of the (primary) packaging
INJECTION /INFUSION	INJECTION /INFUSION			material not in contact with the finished product formulation (such as colour of
100MG/VIA	100MG/VIA		MEDOCHEMIE	flip-off caps, colour code rings on
L	L	9248/23T, 9249/23T	LTD	ampoules, change of needle shield

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				(different plastic used)) - Change that does not affect the product information
				C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package
ULCEDINE FILM COATED TABLETS 40MG	ULCEDINE FILM COATED TABLETS 40MG	7842/23T	CODAL- SYNTO LIMITED	Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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	ALZEDEM	7043/231		B.I.z B.I.z - Quality change - Active
TABLET, FILM COATED 20MG	TABLET, FILM COATED 20MG	9416/23T, 9417/23T, 9418/23T, 9419/23T, 9420/23T, 9421/23T	CODAL- SYNTO LIMITED	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)
SEDISTRE SS SLEEP TABLET, FILM COATED 500MG	SEDISTRE SS 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

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				part of the approved dossier - Re-test period/storage period -
				B.I.b.2.d B.I.b.2.d - QUALITY
				CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in
ALLUZIENC	ALLUZIENC			test procedure for active substance or
E	E			starting material/reagent/intermediate
SOLUTION FOR	SOLUTION FOR			used in the manufacturing process of the active substance - Substantial
INJECTION	INJECTION			change to or replacement of a
200	200			biological/ immunological/
SPEYWOO D	SPEYWOO D		IPSEN	immunochemical test method or a method using a biological reagent for a
UNITS/ML	UNITS/ML	7690/23T	PHARMA	biological active substance
				B.II.b.4.f B.II.b.4.f - QUALITY CHANGES - FINISHED PRODUCT -
ALBIOMIN	ALBIOMIN			Manufacture - Change in the batch size
20%	20%			(including batch size ranges) of the
SOLUTION FOR	SOLUTION FOR		BIOTEST	finished product - The scale for a biological/immunological medicinal
INFUSION	INFUSION		PHARMA	product is increased / decreased without
200G/L	200G/L	8351/23T	GMBH	process change (e.g. duplication of line)
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
KORANDIL	KORANDIL		DEMEDIOA	to the relevant Ph. Eur. Monograph -
TABLET 10MG	TABLET 10MG	9852/23T	REMEDICA LTD	Updated certificate from an already approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European Pharmacopoeial Certificate of Suitability
KORANDIL	KORANDIL			to the relevant Ph. Eur. Monograph -
TABLET	TABLET		REMEDICA	Updated certificate from an already
5MG	5MG	9853/23T	LTD	approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in the manufacturing process of the active
				substance For an excipient - European
KODANDU				Pharmacopoeial Certificate of Suitability
KORANDIL TABLET	KORANDIL TABLET		REMEDICA	to the relevant Ph. Eur. Monograph - Updated certificate from an already
20MG	20MG	9851/23T	LTD	approved manufacturer
LONATA EYE	LONATA EYE			B.II.e.1.z B.II.e.1.z - QUALITY
DROPS,	DROPS,			CHANGES - FINISHED PRODUCT -
SOLUTION	SOLUTION			Container closure system - Change in
(50MCG/5M G)/ML	(50MCG/5M G)/ML	6867/23T	PHARMATHE N S.A.	immediate packaging of the finished product - Other changes
HEXAFLU	HEXAFLU		JOHNSON &	C.I.4 C.I.4 - SAFETY, EFFICACY,
DAY &	DAY &	E100/00T	JOHNSON	PHARMACOVIGILANCE CHANGES -
NIGHT	NIGHT	5133/23T	HELLAS	HUMAN AND VETERINARY

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TABLET	TABLET		CONSUMER	MEDICINAL PRODUCTS - Change(s)
500MG/60M	500MG/60M		AE	in the Summary of Product
G AND	G AND			Characteristics, Labelling or Package
500MG/25M	500MG/25M			Leaflet due to new quality, preclinical,
G	G			clinical or pharmacovigilance data
NOPRILAM	NOPRILAM			
500	500			B.II.d.2.d B.II.d.2.d - QUALITY
TABLET,	TABLET,			CHANGES - FINISHED PRODUCT -
FILM	FILM			Control of finished product - Change in
COATED	COATED		BIAL-	test procedure for the finished product -
(500MG/12	(500MG/12	9667/23T, 9668/23T,	PORTELA &	Other changes to a test procedure
5MG)	5MG)	9669/23T	CA, SA	(including replacement or addition)
ALBIOMIN	ALBIOMIN			
20%	20%			
SOLUTION	SOLUTION		DIOTEOT	
FOR	FOR		BIOTEST	B.II.h.z B.II.h.z - QUALITY CHANGES -
INFUSION	INFUSION	7707 (00 T	PHARMA	FINISHED PRODUCT - Adventitious
200G/L	200G/L	7767/23T	GMBH	Agents Safety - Other variation
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
010.475.4.0	010 4 75 4 0			- Submission of a new or updated Ph.
CISATRAC	CISATRAC			Eur. Certificate of suitability or deletion
URIUM	URIUM			of Ph. Eur. certificate of suitability: For
ACCORDP	ACCORDP			an active substance For a starting
HARMA	HARMA			material/reagent/intermediate used in
SOLUTION	SOLUTION			the manufacturing process of the active
FOR	FOR			substance For an excipient - European
INJECTION	INJECTION			Pharmacopoeial Certificate of Suitability
OR	OR		ACCORD	to the relevant Ph. Eur. Monograph -
INFUSION	INFUSION	000 A/00T	HEALTHCARE	Updated certificate from an already
2MG/ML	2MG/ML	8804/23T	S.L.U	approved manufacturer
				C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of product
				Characteristics, Labelling or Package
				Leaflet intended to implement the
AMICOR	AMICOR			outcome of a PRAC signal
TABLET,	TABLET,			recommendation: implementation of
FILM	FILM			wording agreed by the competent
COATED	COATED		MEDOCHEMIE	authority that do not require any further
10MG	10MG	3035/23T	LTD	assessment
				C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of product
				Characteristics, Labelling or Package
	4141005			Leaflet intended to implement the
AMICOR	AMICOR			outcome of a PRAC signal
TABLET,	TABLET,			recommendation: implementation of
FILM	FILM			wording agreed by the competent
COATED	COATED	2022/227	MEDOCHEMIE	authority that do not require any further
40MG	40MG	3033/23T	LTD	
				C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of product
				Characteristics, Labelling or Package
				Leaflet intended to implement the
				outcome of a PRAC signal
TABLET,	TABLET,			recommendation: implementation of
FILM	FILM			wording agreed by the competent
COATED	COATED	2024/22T	MEDOCHEMIE	authority that do not require any further
20MG	20MG	3034/23T	LTD	
	PULMICOR			A.4 A.4 - ADMINISTRATIVE
	Т	0028/227 0020/227	ASTRAZENEC	CHANGES - Change in the name
TURBUHAL	TURBUHAL	9028/23T, 9029/23T	A AB	and/or address of: a manufacturer

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ER	ER			(including where relevant quality control
POWDER	POWDER			testing sites); or an ASMF holder; or a
FOR	FOR			supplier of the active substance, starting
INHALATIO	INHALATIO			material, reagent or intermediate used
N	Ν			in the manufacture of the active
200MCG/D	200MCG/D			substance (where specified in the
OSE	OSE			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
				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
PULMICOR	PULMICOR			technical dossier)
Т	т			A.5.a A.5.a - ADMINISTRATIVE
TURBUHAL	TURBUHAL			CHANGES - Change in the name
ER	ER			and/or address of a
POWDER	POWDER			manufacturer/importer of the finished
FOR	FOR			product (including batch release or
-	-			
INHALATIO	INHALATIO			quality control testing sites) - The
N	N			activities for which the
100MCG/D	100MCG/D		ASTRAZENEC	manufacturer/importer is responsible
OSE	OSE	9030/23T, 9031/23T	A AB	include batch release
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
METRONID	METRONID			an active substance For a starting
AZOLE	AZOLE			material/reagent/intermediate used in
VIOSER	VIOSER			the manufacturing process of the active
SOLUTION	SOLUTION			substance For an excipient - European
FOR	FOR		VIOSER S.A.	Pharmacopoeial Certificate of Suitability
INFUSION	INFUSION		PARENTERAL	to the relevant Ph. Eur. Monograph
500MG/100	500MG/100		SOLUTIONS	New certificate from a new
ML	ML	8539/23T	INDUSTRY	manufacturer (replacement or addition)
				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
PULMOZY	PULMOZY			
				biological/immunological product and
ME	ME			any of the test methods performed at
NEBULISE	NEBULISE			the site is a biological/immunological
R	R			method
SOLUTION	SOLUTION	3195/23T, 3196/23T,		B.II.d.2.a B.II.d.2.a - QUALITY
2500U/2.5M	2500U/2.5M	3197/23T, 3198/23T,	ROCHE	CHANGES - FINISHED PRODUCT -
11	L	3199/23T	(HELLAS) SA	Control of finished product - Change in

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				test procedure for the finished product - Minor changes to an approved test procedure
GRAFALON CONCENT RATE FOR SOLUTION FOR INFUSION 20MG/ML	GRAFALON CONCENT RATE 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
PULMOZY ME NEBULISE R SOLUTION 2500U/2.5M L	PULMOZY ME NEBULISE R SOLUTION 2500U/2.5M L	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 or 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
L TANAFRA EYE DROPS, SOLUTION 50MCG/ML	L TANAFRA EYE DROPS, SOLUTION 50MCG/ML	6755/23T	PHARMATHE N 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	DIOVAN TABLET, FILM COATED 160MG DIOVAN	8337/23T	NOVARTIS IRELAND LIMITED NOVARTIS	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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.7 A.7 - ADMINISTRATIVE
TABLET, FILM	TABLET, FILM	8338/23T	IRELAND LIMITED	CHANGES - Deletion of manufacturing sites for an active substance,

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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 TRINITRAT E STERILE CONCENT RATE 5MG/ML	GLYCERYL TRINITRAT E STERILE CONCENT RATE 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
BOCOUTU RE POWDER FOR SOLUTION FOR INJECTION 100U	BOCOUTU RE POWDER FOR SOLUTION FOR INJECTION 100U	8906/23T, 8907/23T	MERZ PHARMACEU TICALS 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)
BOCOUTU RE POWDER FOR SOLUTION FOR INJECTION 50U	BOCOUTU RE POWDER FOR SOLUTION FOR INJECTION 50U	8908/23T, 8909/23T	MERZ PHARMACEU TICALS 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

500	500			
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: For an active substance For a starting material/reagent/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	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
ABIRATER ONE PHARMAS CIENCE TABLET, FILM COATED 500MG	ABIRATER ONE PHARMAS CIENCE TABLET, FILM COATED 500MG	4142/23T	PHARMASCIE NCE INTERNATION AL 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 INHALATIO N POWDER, HARD CAPSULE 18MCG	SPIRIVA INHALATIO N POWDER, HARD CAPSULE 18MCG	6749/23T	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
OCTAGAM SOLUTION FOR INFUSION 50MG/ML	OCTAGAM SOLUTION FOR INFUSION 50MG/ML	5937/23T	OCTAPHARM A (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
ONDANSE TRON ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	ONDANSE TRON 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
BENDAMU STINE ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 25MG/ML	BENDAMU STINE ACCORD CONCENT RATE 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 CONCENT RATE FOR SOLUTION FOR INFUSION 10MG/ML	NAVIREL CONCENT RATE FOR SOLUTION FOR INFUSION 10MG/ML	7600/23T	MEDAC GESELLSCHA FT FUR KLINISCHE SPEZIALPRAP ARATE 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)*
PANTOPRA ZOLE TAD TABLET, GASTRO- RESISTAN T 40MG	PANTOPRA ZOLE TAD TABLET, GASTRO- RESISTAN T 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/importe	
B.II.b.1.a B.II.b.1.a - (
CHANGES - FINISH	
Manufacture - Replace	ement or addition
of a manufacturing si	
the manufacturing pro	
finished product - Sec	condary packaging
site B.II.b.1.b B.II.b.1.b - 0	
CHANGES - FINISH	
Manufacture - Replace	
of a manufacturing si	te for part or all of
the manufacturing pro	
finished product - Prin	mary packaging
B.II.e.1.a.1 B.II.e.1.a.	1 - QUALITY
CHANGES - FINISH	ED PRODUCT -
Container closure sys	
immediate packaging	
product - Qualitative	
composition - Solid p	namaceutical
A.5.b A.5.b - ADMIN	ISTRATIVE
CHANGES - Change	
and/or address of a	
manufacturer/importe	
product (including ba	
quality control testing activities for which the	
manufacturer/importe	
not include batch rele	-
B.II.b.1.a B.II.b.1.a - 0	QUALITY
CHANGES - FINISH	
Manufacture - Replac	
of a manufacturing si	
the manufacturing pro finished product - Sec	
site	condary packaging
B.II.b.1.b B.II.b.1.b - (QUALITY
CHANGES - FINISH	ED PRODUCT -
Manufacture - Replac	
of a manufacturing si	
the manufacturing pro finished product - Prin	
site	nary packaging
B.II.e.1.a.1 B.II.e.1.a.	1 - QUALITY
PANTOPRA PANTOPRA CHANGES - FINISH	
ZOLE TAD ZOLE TAD Container closure sys	
TABLET, TABLET, immediate packaging GASTRO- GASTRO- product - Qualitative a	
GASTRO- GASTRO- product - Qualitative - RESISTAN RESISTAN 6265/23T, 6266/23T, TAD PHARMA composition - Solid p	
T 20MG T 20MG 6267/23T, 6268/23T GMBH forms	
HALEON	
HELLAS	
SINGLE B.IV.1.a.1 B.IV.1.a.1	
MEMBER CHANGES - Medical SOCIETE of a measuring or adu	
ANONYME - Addition or replacen	
SINECOD SINECOD (TRADING AS which is not an integr	
SYRUP SYRUP HALEON primary packaging - [
0.15% 0.15% 8942/23T HELLAS) marking	
PULMICOR PULMICOR B.III.1.a.2 B.III.1.a.2	
T T CHANGES - CEP/TS TURBUHAL TURBUHAL Submission of a new	
ER ER ER EUR	
POWDER POWDER of Ph. Eur. certificate	
FOR FOR 9659/23T, 9660/23T, ASTRAZENEC an active substance I	
	mediate used in

N 200MCG/D OSE	N 200MCG/D OSE			the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
PULMICOR T	PULMICOR T			Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
TURBUHAL	TURBUHAL			an active substance For a starting
ER POWDER	ER POWDER			material/reagent/intermediate used in the manufacturing process of the active
FOR	FOR			substance For an excipient - European
INHALATIO N	INHALATIO N			Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
100MCG/D	100MCG/D	9662/23T, 9663/23T,	ASTRAZENEC	Updated certificate from an already
OSE	OSE	9664/23T	A AB	approved manufacturer
				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
TRISEQUE	TRISEQUE			order to adapt to a recommendation of a competent authority , e.g. a Core
NS	NS			SmPC, following the assessment of an
TABLET,	TABLET,		NOVO	Urgent Safety Restriction etc.
FILM COATED	FILM COATED	9284/23T	NORDISK HELLAS LTD	Implementation of wording agreed by the competent authority.
				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
		8978/23T, 8979/23T,		CHANGES - FINISHED PROD B.II.b.5.c B.II.b.5.c - QUALITY
		8980/23T, 8981/23T,		CHANGES - FINISHED PROD
		8982/23T, 8983/23T, 8984/23T, 8985/23T,		B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PROD
		8986/23T, 8987/23T,		B.II.d.1.c B.II.d.1.c - QUALITY
		8988/23T, 8989/23T, 8990/23T, 8991/23T,		CHANGES - FINISHED PROD B.II.d.1.z B.II.d.1.z - QUALITY
		8992/23T, 8993/23T,		CHANGES - FINISHED PROD
CANESTEN	CANESTEN	8994/23T, 8995/23T, 8996/23T, 8997/23T,		B.II.d.1.d B.II.d.1.d - QUALITY CHANGES - FINISHED PROD
VAGINAL	VAGINAL	8998/23T, 8999/23T,	BAYER	B.II.d.2.a B.II.d.2.a - QUALITY
CREAM 2%	CREAM 2%	9000/23T	HELLAS ABEE	CHANGES - FINISHED PROD
TRIATEC TABLET	TRIATEC TABLET		SANOFI WINTHROP	A.1 A.1 - ADMINISTRATIVE
2.5MG	2.5MG	8739/23T	INDUSTRIE.	CHANGES - Change in the name

				and/or address of the marketing authorisation holder
				A.1 A.1 - ADMINISTRATIVE
TRIATEC	TRIATEC		SANOFI	CHANGES - Change in the name
TABLET	TABLET		WINTHROP	and/or address of the marketing
5MG	5MG	8738/23T	INDUSTRIE.	authorisation holder
				B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
RIVAROLT	RIVAROLT			Stability - Change in the shelf-life or
O TABLET,	O TABLET,			storage conditions of the finished
FILM	FILM			product - Extension of the shelf life of
COATED 2.5MG	COATED 2.5MG	7673/23T	TAD PHARMA GMBH	the finished product - As packaged for sale (supported by real time data)
2.5101G	2.5101G	1013/231	GIVIDH	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
RIVAROLT	RIVAROLT			Stability - Change in the shelf-life or
O TABLET,	O TABLET,			storage conditions of the finished
FILM	FILM			product - Extension of the shelf life of
COATED	COATED		TAD PHARMA	the finished product - As packaged for
10MG	10MG	7676/23T	GMBH	sale (supported by real time data)
				B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
RIVAROLT	RIVAROLT			Stability - Change in the shelf-life or
O TABLET,	O TABLET,			storage conditions of the finished
FILM COATED	FILM COATED		TAD PHARMA	product - Extension of the shelf life of the finished product - As packaged for
15MG	15MG	7675/23T	GMBH	
IJING		1010/201	GiviDi i	sale (supported by real time data) B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
RIVAROLT	RIVAROLT			Stability - Change in the shelf-life or
O TABLET,	O TABLET,			storage conditions of the finished
FILM	FILM			product - Extension of the shelf life of
COATED	COATED		TAD PHARMA	the finished product - As packaged for
20MG	20MG	7674/23T	GMBH	sale (supported by real time data)
VINCRISTI	VINCRISTI			A.5.a A.5.a - ADMINISTRATIVE
NE	NE			CHANGES - Change in the name
SULPHATE	SULPHATE			and/or address of a
SOLUTION	SOLUTION FOR			manufacturer/importer of the finished
FOR INJECTION	INJECTION			product (including batch release or quality control testing sites) - The
OR	OR			activities for which the
INFUSION	INFUSION		PFIZER	manufacturer/importer is responsible
1MG/ML	1MG/ML	9055/23T	HELLAS AE	include batch release
			-	C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
RAMI-	RAMI-			MEDICINAL PRODUCTS - Change(s)
AMLO	AMLO		IASIS	in the Summary of Product
CAPSULE,	CAPSULE,		PHARMACEU	Characteristics, Labelling or Package
HARD	HARD	2121/22T 2270/22T	TICALS	Leaflet due to new quality, preclinical,
(2.5+5)MG	(2.5+5)MG	2121/23T, 2278/23T	HELLAS SA	clinical or pharmacovigilance data C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
RAMI-	RAMI-			MEDICINAL PRODUCTS - Change(s)
AMLO	AMLO		IASIS	in the Summary of Product
CAPSULE,	CAPSULE,		PHARMACEU	Characteristics, Labelling or Package
HARD	HARD		TICALS	Leaflet due to new quality, preclinical,
(5+10)MG	(5+10)MG	2119/23T, 2276/23T	HELLAS SA	clinical or pharmacovigilance data
				C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
DAN	DANG			
RAMI-	RAMI-			MEDICINAL PRODUCTS - Change(s)
AMLO CAPSULE,	AMLO CAPSULE,		IASIS PHARMACEU	in the Summary of Product Characteristics, Labelling or Package
HARD	HARD		TICALS	Leaflet due to new quality, preclinical,
(10+5)MG	(10+5)MG	2118/23T, 2275/23T	HELLAS SA	clinical or pharmacovigilance data
RAMI-	RAMI-			C.I.4 C.I.4 - SAFETY, EFFICACY,
AMLO	AMLO		IASIS	PHARMACOVIGILANCE CHANGES -
CAPSULE,	CAPSULE,	2117/23T, 2274/23T	PHARMACEU	HUMAN AND VETERINARY
		• •	*	•

(10+10)MG (10+10)MG HELLAS SA in the Summary of Product RAMI- RAMI- AMLO RAMI- AMLO RA	HARD	HARD		TICALS	MEDICINAL PRODUCTS - Change(s)
RAMI- RAMI- AMLO CAPSULE, HARD HARD RAMI- AMLO CAPSULE, HARD RAMI- MLO CAPSULE, HARD PHARMACOV (CAPSULE, HARD PHARMACUT HARD PHARMACUT CLAS PHARMACUT Characteristics, Labelling or Package Latelfet due to new quality, preclinical, clinical or pharmacovigliance data. (5+5)MG 2120/23T, 2277/23T CL4 Share(s) in the Summary of Product Characteristics, Labelling or Package Latelfet due to new quality, preclinical, clinical or pharmacovigliance data. CL4 Characteristics, Labelling or Package Latelfet due to new quality, preclinical, clinical or pharmacovigliance data. CUTIVATE CUTIVATE CL4 Characteristics, Labelling or Product Characteristics, Labelling or Package Latelfet due to new quality, preclinical, clinical or pharmacovigliance data. 0.05% 8287/23T, 8288/23T CL4 CLA SALTIS LATIS LATI	(10+10)MG	(10+10)MG			in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
CUTIVATE CUTIVATE CUTIVATE CUTIVATE CREAM 0.05% 8287/23T, 8288/23T BAYER Baser CREAM CREAM CIAL 1- SLATERY EFFICACY 0.05% 8287/23T, 8288/23T LIMITED PHARMACOVIGILANCE CHANGES - HUMAN AND VEREINARY MEDICIGNAL PRODUCTS - Other Variation BLa.1.F.B.La.1.F.QUALITY CHANGES - Manufacture of a starting material/reagent/intermodate used in the manufacture of a st	AMLO CAPSULE, HARD	AMLO CAPSULE, HARD	2120/23T, 2277/23T	PHARMACEU TICALS	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
- 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 sites)CANESTEN CREAM 1%CANESTEN CREAM 1%BAYER 9562/23TBAYER HELLAS ABEE placeB.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturer (including where relevant quality control testing sites) of the active substance or change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the anaufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the anaufacturer (including where relevant quality control testing sites) of the active substance where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Change to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes placeCANESTEN CUTANEO US SOLUTION 1%CANESTEN SOLUTION SOLUTIONBAYER HELLAS ABEE1% 1%9561/23TBAYER HELLAS ABEE2B.I.a.1.f.B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture -	CREAM	CREAM	8287/23T, 8288/23T	KLINE (IRELAND)	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 CUTANEO USCANESTEN CUTANEO USCANESTEN CUTANEO USCANESTEN SOLUTION 1%P561/23TBAYER HELLAS ABEEB.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 placeCANESTEN CANESTEN CANESTENCANESTEN			9562/23T		- 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
1% 9561/23T HELLAS ABEE place CANESTEN CANESTEN B.I.a.1.f B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture -	CUTANEO US	CUTANEO US			- 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
CANESTEN CANESTEN - ACTIVE SUBSTANCE - Manufacture -			9561/23T		
CUTANEO CUTANEO Change in the manufacturer of a starting material/reagent/intermediate used in solution US US material/reagent/intermediate used in the manufacturing process of the active SOLUTION SOLUTION BAYER the manufacturing process of the active 1% 1% 9561/23T HELLAS ABEE substance or change in the	CUTANEO US SOLUTION	CUTANEO US SOLUTION	0561/23T		- ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active

				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 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 A.7 A.7 - ADMINISTRATIVE
TRIVERAM TABLET, FILM COATED 40MG/10M G/10MG	TRIVERAM TABLET, FILM COATED 40MG/10M G/10MG	4872/23T	LES LABORATOIR ES SERVIER	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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/5MG	TRIVERAM TABLET, FILM COATED 20MG/10M G/5MG	4870/23T	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/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 B.III.1.a.2 B.III.1.a.2 - QUALITY
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	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -

VALSARTA VALSARTA VALSARTA VALSARTA VALSARTA VALSARTA VALSARTA VALSARTA VALSARTA VALSARTA N JUBILANT TABLET, FILM COATED 9006/23T, 9097/23T, JUBILANT TABLET, FILM COATED BOMG 9098/23T JUBILANT TABLET, FILM COATED BOMG 9098/23T JUBILANT TABLET, FILM COATED BOMG 9098/23T					Updated certificate from an already
VALSARTA N JUBILANT TABLET, FILM COATED BOMGVALSARTA N N JUBILANT TABLET, FILM COATED BOMGVALSARTA N N JUBILANT TABLET, FILM COATED BOMG9096/23T, 9097/23T, 9098/23TJUBILANT TICALS NVCHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the release or quality control testing sites) - The activities for which the release or quality control testing sites) - The activities for which the lease or quality control testing sites) - The activities for which the lease or quality control testing sites) - The activities for which the leases or quality control testing sites) - The activities for which the lease or quality control testing sites) - The activities for which the lease or quality control testing sites) - The activities for which the lease or and/or address of a manufacturer/importer or the finished material, reagent or intermediate used in the manufacture or intermediate used in the manufacturer or 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 or the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer or the finished product (includi					approved manufacturer
VALSARTA N JUBILANT TABLET, FILM COATED BOMGVALSARTA N SUMGVALSARTA N SUMGASARTA SARTA N SUBILANT TABLET, FILM COATED BOMGVALSARTA N SUMGJUBILANT TABLET, FILM COATED SUMGSummary SUBILANT TABLET, FILM COATED SUMG9096/23T, 9097/23T, 9096/23T, 9097/23T, 9096/23T, 9097/23T,JUBILANT TICALS NVAn and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites). The activities for which the manufacturer/importer of the finished product (including batch release or quality control testing sites). The activities for which the manufacturer/importer of the finished product (including batch release or quality control testing sites). The activities for which the manufacturer/importer of the finished product (including batch release or quality control testing sites). The activities for which the manufacturer/importer is responsible do manufacturer/importer is responsible do in the cutive substance, starting manufacturer/importer of the finished product (including where relevant quality control testing sites). The activities for which the manufacturer/importer of the finished product (including where relevant quality control testing sites). The activities for which the manufacturer/importer of the finished product (including where relevant quality control testing sites). The activities for					_
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PENOPEN TABLET, FILM COATED PENOPEN TABLET, FILM COATED PENOPEN TABLET, FILM COATED PENOPEN TABLET, FILM COATED PENOPEN TABLET, FILM COATED REMEDICA B540/23T REMEDICA Characteristics, Labeling or Package Leaflet of a generichybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which on ew additional data is required to be submitted by the MAH PENOPEN TABLET, FILM COATED PENOPEN TABLET, FILM COATED REMEDICA REMEDICA PENOPEN TABLET, FILM COATED PENOPEN TABLET, FILM COATED REMEDICA C.12.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generichybrid/biosimilar medicinal products following SouMG 8541/23T REMEDICA REMEDICA ADMINISTRATIVE CHANGES - Change in the name and/or address of 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 or quality control testing sites) - The activities for which the manufacturer/importer is responsible on on on include batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible on on on include batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible on on on include batch release or quality control testing sites) - The activities for which the manufacture - Change to importer, product (including bath release or quality control testing siten produc					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
PENOPEN TABLET, FILM PENOPEN TABLET, FILM PENOPEN TABLET, FILM COATED 800MG PENOPEN TABLET, FILM COATED 800MG PENOPEN TABLET, FILM COATED 800MG REMEDICA REMEDICA LTD REMEDICA ALA HARD ACA a A.5.a - ADMINISTRATIVE REMEDICA REMEDICA 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 tho release or quality control testing sites) - The activities for which the manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release or quality control testing sites) - The activities for which the manufac	TABLET, FILM COATED	TABLET, FILM COATED	8540/23T	-	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TENORETI COATEDTENORETI GCHANGES - Change in the name and/or address of 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 a.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the 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 - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes placePIPERACIL LIN +PIPERACIL LIN +MYLAN IRELANDA.2.b A.2.b - ADMINISTRATIVE	TABLET, FILM COATED	TABLET, FILM COATED	8541/23T	-	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the
TAZOBACT TAZOBACT 5932/23T LIMITED CHANGES - Change in the (invented)	TENORETI C TABLET, FILM COATED 100MG/25M G PIPERACIL	TENORETI C TABLET, FILM COATED 100MG/25M G PIPERACIL	9608/23T, 9609/23T, 9610/23T	ATNAHS PHARMA NETHERLAND S B.V. MYLAN	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

	1	1		1
AM/GENER	AM/GENER			name of the medicinal product - for
ICS POWDER	ICS POWDER			Nationally Authorised Products
FOR	FOR			
SOLUTION	SOLUTION			
FOR	FOR			
INJECTION	INJECTION			
/INFUSION	/INFUSION			
(2G/0.25G)/	(2G/0.25G)/			
VIAL	VIAL			
PIPERACIL	PIPERACIL			
LIN +	LIN +			
TAZOBACT	TAZOBACT			
AM/GENER	AM/GENER			
ICS POWDER	ICS POWDER			
FOR	FOR			
SOLUTION	SOLUTION			
FOR	FOR			
INJECTION	INJECTION			A.2.b A.2.b - ADMINISTRATIVE
/INFUSION	/INFUSION		MYLAN	CHANGES - Change in the (invented)
(4G/0.5G)/V	(4G/0.5G)/V		IRELAND	name of the medicinal product - for
IAL	IAL	5931/23T	LIMITED	Nationally Authorised Products
TRIATEC	TRIATEC			A.1 A.1 - ADMINISTRATIVE
PLUS	PLUS		SANOFI	CHANGES - Change in the name
TABLET	TABLET	0000/007	WINTHROP	and/or address of the marketing
5MG/25MG	5MG/25MG	8686/23T	INDUSTRIE.	authorisation holder
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
OCTAPLEX	OCTAPLEX			Pharmacopoeial Certificate of Suitability
POWDER	POWDER			to the relevant Ph. Eur. Monograph -
AND	AND			Updated certificate from an already
SOLVENT	SOLVENT			approved manufacturer
FOR SOLUTION	FOR SOLUTION			B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT -
FOR	FOR			Control of excipients - Change in test
INFUSION	INFUSION		OCTAPHARM	procedure for an excipient - Minor
500IU	500IU	8278/23T, 8279/23T	A (IP) SPRL	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
OCTAPLEX	OCTAPLEX			substance For an excipient - European Pharmacopoeial Certificate of Suitability
POWDER	POWDER			to the relevant Ph. Eur. Monograph -
AND	AND			Updated certificate from an already
SOLVENT	SOLVENT			approved manufacturer
FOR	FOR			B.II.c.2.a B.II.c.2.a - QUALITY
SOLUTION	SOLUTION			CHANGES - FINISHED PRODUCT -
FOR	FOR			Control of excipients - Change in test
INFUSION	INFUSION		OCTAPHARM	procedure for an excipient - Minor
1000IU	1000IU	8276/23T, 8277/23T	A (IP) SPRL	changes to an approved test procedure
OCTANINE	OCTANINE			B.III.1.a.2 B.III.1.a.2 - QUALITY
POWDER	POWDER			CHANGES - CEP/TSE/MONOGRAPHS
AND	AND			- Submission of a new or updated Ph.
SOLVENT	SOLVENT			Eur. Certificate of suitability or deletion
FOR SOLUTION	FOR SOLUTION		OCTAPHARM	of Ph. Eur. certificate of suitability: For an active substance For a starting
FOR	FOR	8274/23T, 8275/23T	A (IP) SPRL	material/reagent/intermediate used in
		0214/201,0210/201		material/reagent/interneutate useu in

INJECTION 500IU/VIAL	INJECTION 500IU/VIAL			the manufacturing process of the active substance For an excipient - European
(100IU/ML)	(100IU/ML)			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
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
OCTANINE	OCTANINE			the manufacturing process of the active
POWDER	POWDER			substance For an excipient - European
AND SOLVENT	AND SOLVENT			Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
FOR	FOR			Updated certificate from an already
SOLUTION	SOLUTION			approved manufacturer
FOR INJECTION	FOR INJECTION			B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PRODUCT -
1000IU/VIA	1000IU/VIA			Control of excipients - Change in test
L(100IU/ML	L(100IU/ML		OCTAPHARM	procedure for an excipient - Minor
))	8272/23T, 8273/23T	A (IP) SPRL	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
CO-	CO-			the manufacturing process of the active
DIOVAN TABLET,	DIOVAN TABLET,			substance For an excipient - European Pharmacopoeial Certificate of Suitability
FILM	FILM		NOVARTIS	to the relevant Ph. Eur. Monograph -
COATED	COATED	5 455 /00 T	IRELAND	Updated certificate from an already
80/12.5MG	80/12.5MG	5455/23T	LIMITED	approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
DIOVAN TABLET,	DIOVAN TABLET,			substance For an excipient - European Pharmacopoeial Certificate of Suitability
FILM	FILM		NOVARTIS	to the relevant Ph. Eur. Monograph -
COATED	COATED	5450/22T		Updated certificate from an already
160MG	160MG	5450/23T	LIMITED	approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
DIOVAN	DIOVAN			the manufacturing process of the active
TABLET,	TABLET,			substance For an excipient - European Pharmacopoeial Certificate of Suitability
FILM	FILM		NOVARTIS	to the relevant Ph. Eur. Monograph -
COATED	COATED	5451/00T		Updated certificate from an already
80MG	80MG	5451/23T	LIMITED	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 INHALATIO N (2.5MCG/2. 5MCG)/DO SE	SPIOLTO RESPIMAT SOLUTION FOR INHALATIO N (2.5MCG/2. 5MCG)/DO SE	4689/23T, 4690/23T, 4691/23T, 4692/23T, 4693/23T	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
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 - 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) 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
DIOVAN	DIOVAN			substance (where specified in the technical dossier) where no Ph. Eur.
TABLET,	TABLET,			Certificate of Suitability is part of the
FILM	FILM		NOVARTIS	approved dossier; or a manufacturer of
COATED 160MG	COATED 160MG	7046/23T	IRELAND LIMITED	a novel excipient (where specified in the technical dossier)
		1070/201		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
DIOVAN	DIOVAN			technical dossier) where no Ph. Eur.
TABLET,	TABLET,			Certificate of Suitability is part of the
FILM COATED	FILM COATED		NOVARTIS IRELAND	approved dossier; or a manufacturer of a novel excipient (where specified in the
40MG	40MG	7047/23T	LIMITED	technical 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.
TABLET, FILM	TABLET, FILM		NOVARTIS	Certificate of Suitability is part of the approved dossier; or a manufacturer of
COATED	COATED		IRELAND	a novel excipient (where specified in the
40MG	40MG	7047/23T	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
DIOVAN	DIOVAN			substance (where specified in the technical dossier) where no Ph. Eur.
TABLET,	TABLET,			Certificate of Suitability is part of the
FILM	FILM		NOVARTIS	approved dossier; or a manufacturer of
COATED 80MG	COATED 80MG	7045/23T	IRELAND LIMITED	a novel excipient (where specified in the technical dossier)
				A.4 A.4 - ADMINISTRATIVE
				CHANGES - Change in the name
TABLET, FILM	TABLET, FILM		NOVARTIS	and/or address of: a manufacturer (including where relevant quality control
COATED	COATED		IRELAND	testing sites); or an ASMF holder; or a
80MG	80MG	7045/23T	LIMITED	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.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
CO-	CO-			in the manufacture of the active substance (where specified in the
DIOVAN	DIOVAN			technical dossier) where no Ph. Eur.
TABLET, FILM	TABLET, FILM		NOVARTIS	Certificate of Suitability is part of the approved dossier; or a manufacturer of
COATED	COATED		IRELAND	a novel excipient (where specified in the
160/12.5MG	160/12.5MG	7043/23T	LIMITED	technical 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
DIOVAN	DIOVAN			technical dossier) where no Ph. Eur. Certificate of Suitability is part of the
ORAL	ORAL		NOVARTIS	approved dossier; or a manufacturer of
SOLUTION 3MG/ML	SOLUTION 3MG/ML	7048/23T	IRELAND LIMITED	a novel excipient (where specified in the technical dossier)
	SING/ME	1040/201		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.
DIOVAN	DIOVAN			Certificate of Suitability is part of the
ORAL SOLUTION	ORAL SOLUTION		NOVARTIS IRELAND	approved dossier; or a manufacturer of a novel excipient (where specified in the
3MG/ML	3MG/ML	7048/23T	LIMITED	technical 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
DELIPOST	DELIPOST			substance For an excipient - European
TABLET, FILM	TABLET, FILM			Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
COATED	COATED			Updated certificate from an already
40MG	40MG	7275/23T	RAFARM S.A.	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
DELIPOST	DELIPOST			- Submission of a new or updated Ph.
TABLET, FILM	TABLET, FILM			Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
COATED	COATED			an active substance For a starting
10MG	10MG	7277/23T	RAFARM S.A.	material/reagent/intermediate used in

				the manufacturing process of 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.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
				the manufacturing process of the active
DELIPOST	DELIPOST			substance For an excipient - European
TABLET,	TABLET,			Pharmacopoeial Certificate of Suitability
FILM	FILM			to the relevant Ph. Eur. Monograph -
COATED	COATED			Updated certificate from an already
20MG	20MG	7276/23T	RAFARM S.A.	approved manufacturer
				C.I.11.b C.I.11.b - SAFETY,
				EFFICACY, PHARMACOVIGILANCE
NORDITRO	NORDITRO			
PIN FLEXPRO	PIN FLEXPRO			VETERINARY MEDICINAL PRODUCTS - Introduction of, or
SOLUTION	SOLUTION			change(s) to, the obligations and
FOR	FOR			conditions of a marketing authorisation,
INJECTION	INJECTION			including the risk management plan -
IN A PRE-	IN A PRE-			Implementation of change(s) which
FILLED	FILLED			require to be further substantiated by
PEN	PEN			new additional data to be submitted by
10MG/1.5M	10MG/1.5M	4 4 9 9 /9 9 7	NOVO	the MAH where significant assessment
L	L	1128/23T	NORDISK A/S	by the competent authority is required*
				C.I.11.b C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE
NORDITRO	NORDITRO			CHANGES - HUMAN AND
PIN	PIN			VETERINARY MEDICINAL
FLEXPRO	FLEXPRO			PRODUCTS - Introduction of, or
SOLUTION	SOLUTION			change(s) to, the obligations and
FOR	FOR			conditions of a marketing authorisation,
INJECTION	INJECTION			including the risk management plan -
IN A PRE-	IN A PRE-			Implementation of change(s) which
FILLED PEN	FILLED PEN			require to be further substantiated by new additional data to be submitted by
15MG/1.5M	15MG/1.5M		NOVO	the MAH where significant assessment
L	L	1127/23T	NORDISK A/S	by the competent authority is required*
				C.I.11.b C.I.11.b - SAFETY,
				EFFICACY, PHARMACOVIGILANCE
				CHANGES - HUMAN AND
NORDITRO	NORDITRO			VETERINARY MEDICINAL
				PRODUCTS - Introduction of, or
FLEXPRO SOLUTION	FLEXPRO SOLUTION			change(s) to, the obligations and conditions of a marketing authorisation,
FOR	FOR			including the risk management plan -
INJECTION	INJECTION			Implementation of change(s) which
IN A PRE-	IN A PRE-			require to be further substantiated by
FILLED	FILLED			new additional data to be submitted by
PEN	PEN		NOVO	the MAH where significant assessment
5MG/1.5ML	5MG/1.5ML	1129/23T	NORDISK A/S	by the competent authority is required*
NORDITRO	NORDITRO			C.I.11.b C.I.11.b - SAFETY,
PIN NORDIFLE	PIN NORDIFLE			EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND
X	X			VETERINARY MEDICINAL
SOLUTION	SOLUTION			PRODUCTS - Introduction of, or
FOR	FOR			change(s) to, the obligations and
INJECTION	INJECTION			conditions of a marketing authorisation,
IN A PRE-	IN A PRE-			including the risk management plan -
			NOVO	Implementation of change(s) which
PEN 5MG/1.5ML	PEN 5MG/1.5ML	1126/23T	NOVO NORDISK A/S	require to be further substantiated by new additional data to be submitted by
		1120/201	NONDION A/O	now additional data to be submitted by

F		1	1	1
				the MAH where significant assessment by the competent authority is required*
NORDITRO PIN NORDIFLE X SOLUTION FOR INJECTION IN A PRE- FILLED PEN 15MG/1.5M L	NORDITRO PIN NORDIFLE X SOLUTION FOR INJECTION IN A PRE- FILLED PEN 15MG/1.5M L	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*
NORDITRO PIN NORDIFLE X SOLUTION FOR INJECTION IN A PRE- FILLED PEN 10MG/1.5M L	NORDITRO PIN NORDIFLE X SOLUTION FOR INJECTION IN A PRE- FILLED PEN 10MG/1.5M L	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, CHEWABL E 4MG	SINGULAIR TABLET, CHEWABL E 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/80M G	INEGY TABLET 10MG/80M G	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
				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
INEGY	INEGY			of a summary of pharmacovigilance system, changes in QPPV (including
TABLET	TABLET			contact details) and/or changes in the
10MG/10M	10MG/10M		N.V.	Pharmacovigilance System Master File
G	G	8160/23T	ORGANON	(PSMF) location
<u> </u>	0	0100/201		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
INEGY	INEGY			system, changes in QPPV (including
TABLET	TABLET			contact details) and/or changes in the
10MG/20M	10MG/20M		N.V.	Pharmacovigilance System Master File
G	G	8159/23T	ORGANON	(PSMF) location
				C.I.8.a C.I.8.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Introduction
				of, or changes to, a summary of pharmacovigilance system for medicinal
LIPTRUZET	LIPTRUZET			products for human use* - Introduction
TABLET,	TABLET,			of a summary of pharmacovigilance
FILM	FILM			system, changes in QPPV (including
COATED	COATED			contact details) and/or changes in the
10MG/40M	10MG/40M		N.V.	Pharmacovigilance System Master File
G	G	8167/23T	ORGANON	(PSMF) location
				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
TABLET, FILM	TABLET, FILM			of a summary of pharmacovigilance
COATED				system, changes in QPPV (including contact details) and/or changes in the
10MG/80M	10MG/80M		N.V.	Pharmacovigilance System Master File
G	G	8166/23T	ORGANON	(PSMF) location
L	- ~			C.I.8.a C.I.8.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Introduction
				of, or changes to, a summary of
				pharmacovigilance system for medicinal
				products for human use* - Introduction
				of a summary of pharmacovigilance
INEGY	INEGY			system, changes in QPPV (including
TABLET	TABLET			contact details) and/or changes in the
10MG/40M G	10MG/40M G	8158/23T	N.V. ORGANON	Pharmacovigilance System Master File (PSMF) location
LIPTRUZET	LIPTRUZET	0100/201	UNGANUN	C.I.8.a C.I.8.a - SAFETY, EFFICACY,
TABLET,	TABLET,			PHARMACOVIGILANCE CHANGES -
FILM	FILM		N.V.	HUMAN AND VETERINARY
COATED	COATED	8168/23T	ORGANON	MEDICINAL PRODUCTS - Introduction

10MG/20M G of, or changes to, a summary of pharmacoviglance system for medicinal products for human use" - httoduction of a summary of pharmacoviglance system Master File (FSMF) location CLIB					
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ARCOXIA TABLET, FILMARCOXIA TABLET, FILMARCOXIA TABLET, FILMN.V.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 120MGARCOXIAN.V.Pharmacovigilance System Master File (PSMF) locationARCOXIAARCOXIAN.V.	50MG	50MG	8164/231	ORGANON	
ARCOXIA TABLET, FILM COATED 120MGARCOXIA TABLET, FILM ARCOXIAARCOXIA FILM ARCOXIAHUMAN 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 ORGANONARCOXIAARCOXIAARCOXIAN.V.COATED 120MG8154/23TARCOXIAN.V.CI.8.a C.1.8.a - SAFETY, EFFICACY,					
ARCOXIA TABLET, FILMARCOXIA TABLET, FILMARCOXIA TABLET, FILMMEDICINAL 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 120MG120MG120MG8154/23TORGANON(PSMF) locationARCOXIAN.V.N.V.C.I.8.a C.I.8.a - SAFETY, EFFICACY,					
ARCOXIA TABLET, FILMARCOXIA TABLET, FILMARCOXIA TABLET, FILMARCOXIA TABLET, FILMof, 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 120MG120MG120MG8154/23TORGANON(PSMF) locationARCOXIAARCOXIAN.V.C.I.8.a C.I.8.a - SAFETY, EFFICACY,					HUMAN AND VETERINARY
ARCOXIA TABLET, FILMARCOXIA TABLET, FILMARCOXIA TABLET, FILMARCOXIA TABLET, FILMof, 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 120MG120MG120MG8154/23TORGANON(PSMF) locationARCOXIAARCOXIAN.V.C.I.8.a C.I.8.a - SAFETY, EFFICACY,					MEDICINAL PRODUCTS - Introduction
ARCOXIA TABLET, FILMARCOXIA TABLET, FILMARCOXIA TABLET, FILMpharmacovigilance 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 120MG120MG120MG8154/23TORGANON(PSMF) locationARCOXIAARCOXIAN.V.C.I.8.a C.I.8.a - SAFETY, EFFICACY,					
ARCOXIA TABLET, FILMARCOXIA TABLET, FILMproducts 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 120MG120MG120MG8154/23TORGANON(PSMF) locationARCOXIAARCOXIAN.V.C.I.8.a C.I.8.a - SAFETY, EFFICACY,					
ARCOXIA TABLET, FILMARCOXIA TABLET, FILMof a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File 120MG120MG120MG8154/23TORGANON(PSMF) locationARCOXIAARCOXIAN.V.C.I.8.a C.I.8.a - SAFETY, EFFICACY,					
TABLET, FILMTABLET, FILMTABLET, FILMsystem, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File 120MG120MG120MG8154/23TORGANON(PSMF) locationARCOXIAARCOXIAN.V.C.I.8.a C.I.8.a - SAFETY, EFFICACY,	ARCOXIA	ARCOXIA			
FILM FILM contact details) and/or changes in the COATED COATED N.V. Pharmacovigilance System Master File 120MG 120MG 8154/23T ORGANON (PSMF) location ARCOXIA ARCOXIA N.V. C.I.8.a C.I.8.a - SAFETY, EFFICACY,					
COATEDCOATEDN.V.Pharmacovigilance System Master File120MG120MG8154/23TORGANON(PSMF) locationARCOXIAARCOXIAN.V.C.I.8.a C.I.8.a - SAFETY, EFFICACY,		,			
120MG 120MG 8154/23T ORGANON (PSMF) location ARCOXIA ARCOXIA N.V. C.I.8.a C.I.8.a - SAFETY, EFFICACY,					
ARCOXIA ARCOXIA N.V. C.I.8.a C.I.8.a - SAFETY, EFFICACY,			0454/00T		
			8154/231		
TABLET, TABLET, 8156/23T ORGANON PHARMACOVIGILANCE CHANGES -					
	TABLET,	TABLET,	8156/23T	ORGANON	PHARMACOVIGILANCE CHANGES -

	1	r		I
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
				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
ARCOXIA	ARCOXIA			products for human use* - Introduction of a summary of pharmacovigilance
TABLET, FILM	TABLET, FILM			system, changes in QPPV (including contact details) and/or changes in the
COATED 90MG	COATED 90MG	8155/23T	N.V. ORGANON	Pharmacovigilance System Master File (PSMF) location
				A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
EPLERENO	EPLERENO			and/or address of a
NE ACCORD	NE ACCORD			manufacturer/importer of the finished product (including batch release or
TABLET, FILM	TABLET, FILM		ACCORD	quality control testing sites) - The activities for which the
COATED 25MG	COATED 25MG	8692/23T	HEALTHCARE S.L.U	manufacturer/importer is responsible do not include batch release
20110	20110		0.2.0	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
EPLERENO	EPLERENO			and/or address of a
NE ACCORD	NE ACCORD			manufacturer/importer of the finished product (including batch release or
TABLET, FILM	TABLET, FILM		ACCORD	quality control testing sites) - The activities for which the
COATED 50MG	COATED 50MG	8691/23T	HEALTHCARE S.L.U	manufacturer/importer is responsible do not include batch release
				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
HALDOL DECANOA	HALDOL DECANOA		JANSSEN-	of a summary of pharmacovigilance system, changes in QPPV (including
S	S		CILAG	contact details) and/or changes in the
INJECTION 100MG/1ML	INJECTION 100MG/1ML	8712/23T	AL NV	Pharmacovigilance System Master File (PSMF) location
				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
HALDOL	HALDOL			products for human use* - Introduction of a summary of pharmacovigilance
DECANOA	DECANOA		JANSSEN-	system, changes in QPPV (including
S INJECTION	S INJECTION		CILAG INTERNATION	contact details) and/or changes in the Pharmacovigilance System Master File
50MG/1ML	50MG/1ML	8713/23T	AL NV	(PSMF) location B.III.1.a.2 B.III.1.a.2 - QUALITY
BROXIVAN	BROXIVAN			CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
ORAL	ORAL		MEDOOUENUE	Eur. Certificate of suitability or deletion
SOLUTION 6MG/ML	SOLUTION 6MG/ML	6006/23T, 6007/23T	MEDOCHEMIE LTD	of Ph. Eur. certificate of suitability: For an active substance For a starting

				material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active substance For an excipient - European
BROXIVAN	BROXIVAN			Pharmacopoeial Certificate of Suitability
ORAL SOLUTION	ORAL SOLUTION			to the relevant Ph. Eur. Monograph -
3MG/ML	3MG/ML	6008/23T, 6009/23T	MEDOCHEMIE LTD	Updated certificate from an already approved manufacturer
		· · · ·		B.II.d.1.e B.II.d.1.e - QUALITY
GYNOFLO	GYNOFLO			CHANGES - FINISHED PRODUCT - Control of finished product - Change in
RAN	RAN			the specification parameters and/or
CAPSULE,	CAPSULE,		CODAL-	limits of the finished product - Change
HARD 50MG	HARD 50MG	9276/23T	SYNTO LIMITED	outside the approved specifications limits range
				B.II.d.1.e B.II.d.1.e - QUALITY
GYNOFLO	GYNOFLO			CHANGES - FINISHED PRODUCT - Control of finished product - Change in
RAN	RAN			the specification parameters and/or
CAPSULE,	CAPSULE,		CODAL-	limits of the finished product - Change
HARD 150MG	HARD 150MG	9275/23T	SYNTO LIMITED	outside the approved specifications limits range
BRALTUS	BRALTUS			B.II.b.3.z B.II.b.3.z - QUALITY
INHALATIO N	INHALATIO N			CHANGES - FINISHED PRODUCT - Manufacture - Change in the
POWDER,	POWDER,			manufacturing process of the finished
HARD	HARD CAPSULE			product, including an intermediate used
CAPSULE 10MCG	10MCG	6923/23T	TEVA BV	in the manufacture of the finished product - Other changes
GLYCERIN	GLYCERIN			
E MICROCLY	E MICROCLY			B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT -
SMA FOR	SMA FOR			Manufacture - Change in the batch size
ADULTS	ADULTS		COSTAKIS	(including batch size ranges) of the
ENEMA 2.4G/DOSE	ENEMA 2.4G/DOSE		COSTAKIS TSISIOS &	finished product - Up to 10-fold compared to the originally approved
(2,5ML)	(2,5ML)	9322/23T	CO. LTD	batch size
				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
NORDELO	NORDELO			MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of
Z	Z			pharmacovigilance system for medicinal
				products for human use* - Introduction
RATE FOR SOLUTION	RATE FOR SOLUTION			of a summary of pharmacovigilance system, changes in QPPV (including
FOR	FOR			contact details) and/or changes in the
INFUSION 4MG/5ML	INFUSION 4MG/5ML	8205/23T, 8206/23T	RAFARM S.A.	Pharmacovigilance System Master File (PSMF) location
PAZOREM	PAZOREM			C.I.z C.I.z - SAFETY, EFFICACY,
TABLET, FILM	TABLET, FILM			PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
COATED			REMEDICA	MEDICINAL PRODUCTS - Other
200MG	200MG	351/23T	LTD	variation

	l	1		
				C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
TABLET, FILM	TABLET, FILM			HUMAN AND VETERINARY
COATED	COATED		REMEDICA	MEDICINAL PRODUCTS - Other
400MG	400MG	350/23T	LTD	variation
1001110	1001110	000/201		A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer
				responsible for batch release, site
				where batch control takes place, or
LORANS	LORANS			supplier of a starting material, reagent
TABLET 2MG	TABLET 2MG	9524/23T	MEDOCHEMIE LTD	or excipient (when mentioned in the dossier)*
21010	21010	9324/231		A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer
				responsible for batch release, site
				where batch control takes place, or
LORANS	LORANS			supplier of a starting material, reagent
TABLET	TABLET	0505/007	MEDOCHEMIE	or excipient (when mentioned in the
1MG	1MG	9525/23T	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
IRINOTECA	IRINOTECA			Characteristics, Labelling or Package
N ACCORD	N ACCORD			Leaflet of a generic/hybrid/biosimilar
CONCENT	CONCENT			medicinal products following
RATE FOR	RATE FOR			assessment of the same change for the
SOLUTION	SOLUTION			reference product - Implementation of
FOR	FOR		ACCORD	change(s) for which no new additional
INFUSION 20MG/ML	INFUSION 20MG/ML	5118/23T	HEALTHCARE S.L.U	data is required to be submitted by the MAH
DENTOCAL	DENTOCAL	5110/231	5.L.0	
NE	NE			
SOLUTION	SOLUTION			C.I.z C.I.z - SAFETY, EFFICACY,
FOR	FOR			PHARMACOVIGILANCE CHANGES -
INJECTION	INJECTION		INIBSA	HUMAN AND VETERINARY
40MG/0.01	40MG/0.01		DENTAL	MEDICINAL PRODUCTS - Other
MG/ML	MG/ML	329/23T	S.L.U.	variation
DENTOCAI NE	DENTOCAI NE			
SOLUTION	SOLUTION			C.I.z C.I.z - SAFETY, EFFICACY,
FOR	FOR			PHARMACOVIGILANCE CHANGES -
INJECTION	INJECTION		INIBSA	HUMAN AND VETERINARY
40MG/0.005	40MG/0.005		DENTAL	MEDICINAL PRODUCTS - Other
MG/ML	MG/ML	328/23T	S.L.U.	variation
				B.II.d.2.a B.II.d.2.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
STEROFUN	STEROFUN			test procedure for active substance or
DIN ISO	DIN ISO			starting material/reagent/intermediate
SOLUTION	SOLUTION		B. BRAUN	used in the manufacturing process of
FOR	FOR	8566/23T, 8567/23T,	MELSUNGEN	the active substance - Minor changes to
INFUSION	INFUSION	8568/23T	AG	an approved test procedure
ALBUNOR M 20%	ALBUNOR M 20%			B.V.a.1.d B.V.a.1.d - QUALITY
SOLUTION	SOLUTION		OCTAPHARM	CHANGES - Changes to a marketing authorisation resulting from other
FOR	FOR	8949/23T, 8950/23T	A (IP) SPRL	regulatory procedures - PMF/VAMF -
	101	00 10/201, 0000/201		

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
ALBUNOR M 25% SOLUTION FOR INFUSION 250G/L	ALBUNOR M 25% SOLUTION FOR INFUSION 250G/L	8947/23T, 8948/23T	OCTAPHARM A (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
ALBUNOR M 5% SOLUTION FOR INFUSION 50G/L	ALBUNOR M 5% SOLUTION FOR INFUSION 50G/L	8953/23T, 8954/23T	OCTAPHARM A (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
ALBUNOR M 4% SOLUTION FOR INFUSION 40G/L	ALBUNOR M 4% SOLUTION FOR INFUSION 40G/L	8951/23T, 8952/23T	OCTAPHARM A (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
ROCURONI UM B.BRAUN SOLUTION FOR INJECTION OR INFUSION 10MG/ML	ROCURONI UM 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 HAEMOFIL TRATION, HAEMODIA FILTRATIO N AND HAEMODIA LYSIS BIOSONID	PHOXILIUM SOLUTION FOR HAEMOFIL TRATION, HAEMODIA FILTRATIO N AND HAEMODIA LYSIS BIOSONID	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 C.I.2.a C.I.2.a - SAFETY, EFFICACY,
E NEBULISE	E NEBULISE	9311/23T	HELP S.A.	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

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R	R			MEDICINAL PRODUCTS - Change(s)
SUSPENSI	SUSPENSI			in the Summary of Product
ON	ON			Characteristics, Labelling or Package
0.5MG/2ML	0.5MG/2ML			Leaflet of a generic/hybrid/biosimilar
				medicinal products following
				assessment of the 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.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
BIOSONID	BIOSONID			Leaflet of a generic/hybrid/biosimilar
E	E			medicinal products following
NEBULISE	NEBULISE			assessment of the same change for the
R	R			reference product - Implementation of
SUSPENSI	SUSPENSI			change(s) for which no new additional
ON	ON			data is required to be submitted by the
1MG/2ML	1MG/2ML	9310/23T	HELP S.A.	МАН
INFANRIX	INFANRIX		1	B.II.e.5.b B.II.e.5.b - QUALITY
TETRA	TETRA		GLAXOSMITH	CHANGES - FINISHED PRODUCT -
SUSPENSI	SUSPENSI		KLINE	Container closure system - Change in
ON FOR	ON FOR		BIOLOGICALS	pack size of the finished product -
		9705/22T		
INJECTION	INJECTION	8705/23T	SA	Deletion of pack size(s)
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of 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 -
CLARIPEN	CLARIPEN			MEDICINAL PRODUCTS - Change(s)
TABLET,	TABLET,			in the Summary of Product
FILM	FILM	5264/22T, 5265/22T,	ELPEN	Characteristics, Labelling or Package
COATED	COATED	5266/22T, 5267/22T,	PHARMACEU	Leaflet due to new quality, preclinical,
500MG	500MG	5268/22T, 5269/22T	TICAL CO INC	clinical or pharmacovigilance data
		· · ·		C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
CILODRAL	CILODRAL			procedure concerning PSUR or PASS,
TABLET,	TABLET,			or the outcome of the assessment done
FILM	FILM			by the competent authority under
COATED	COATED		REMEDICA	Articles 45 or 46 of Regulation
10MG	10MG	9450/23T	LTD	1901/2006 - Other variation
UNIG		3400/201		
				C.I.3.z C.I.3.z - SAFETY, EFFICACY,
	au c== · ·			PHARMACOVIGILANCE CHANGES -
CILODRAL	CILODRAL			HUMAN AND VETERINARY
TABLET,	TABLET,			MEDICINAL PRODUCTS - Change(s)
FILM	FILM			in the Summary of Product
COATED	COATED		REMEDICA	Characteristics, Labelling or Package
40MG	40MG	9448/23T	LTD	Leaflet of human medicinal products
10110	10110	0110/201		

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				intended to implement the outcome of a
				procedure 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.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS, or the outcome of the assessment done
TABLET, FILM	TABLET, FILM			by the competent authority under
COATED	COATED		REMEDICA	Articles 45 or 46 of Regulation
20MG	20MG	9449/23T	LTD	1901/2006 - Other variation
				C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Other variation
MYCORIL	MYCORIL			A.3 A.3 - ADMINISTRATIVE CHANGES
CREAM 1%	CREAM 1%		REMEDICA	- Change in name of the active
W/W	W/W	9121/23T, 9122/23T	LTD	substance or of an excipient
				B.II.b.4.a B.II.b.4.a - QUALITY
BOTAFEX	BOTAFEX			CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size
CUTANEO	CUTANEO			(including batch size ranges) of the
US	US			finished product - Up to 10-fold
SOLUTION	SOLUTION		PHARMEX	compared to the originally approved
5% (W/V)	5% (W/V)	9378/23T	S.A.	batch size
				B.II.d.2.c B.II.d.2.c - QUALITY
MENOPUR	MENOPUR			CHANGES - FINISHED PRODUCT - Control of finished product - Change in
POWDER	POWDER			test procedure for the finished product -
AND	AND			Substantial change to, or replacement
SOLVENT	SOLVENT			of, a biological/ immunological/
FOR	FOR			immunochemical test method or a
SOLUTION FOR	SOLUTION FOR		FERRING	method using a biological reagent or replacement of a biological reference
INJECTION	INJECTION		HELLAS	preparation not covered by an approved
1200IU	1200IU	1326/23T	MEPE	protocol
				B.II.d.2.c B.II.d.2.c - QUALITY
	MENODUD			CHANGES - FINISHED PRODUCT -
MENOPUR POWDER				Control of finished product - Change in
AND	POWDER AND			test procedure for the finished product - Substantial change to, or replacement
SOLVENT	SOLVENT			of, a biological/ immunological/
FOR	FOR			immunochemical test method or a
SOLUTION	SOLUTION			method using a biological reagent or
FOR	FOR		FERRING	replacement of a biological reference
INJECTION 600IU	INJECTION 600IU	1327/23T	HELLAS MEPE	preparation not covered by an approved protocol
	00010			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
ATANTO	ATANTO			system, changes in QPPV (including
CAPSULE,	CAPSULE,			contact details) and/or changes in the
HARD	HARD	9604/22T	PHARMATHE	Pharmacovigilance System Master File
80MG	80MG	8694/23T	N S.A.	(PSMF) location
	ATANTO		PHARMATHE	C.I.8.a C.I.8.a - SAFETY, EFFICACY,

	· · ·			· · · · · · · · · · · · · · · · · · ·
HARD	HARD			HUMAN AND VETERINARY
125MG	125MG			MEDICINAL PRODUCTS - Introduction
AND 80MG	AND 80MG			of, or changes to, a summary of
				pharmacovigilance system for medicinal
				products for human use* - Introduction
				of a summary of pharmacovigilance
				system, changes in QPPV (including
				contact details) and/or changes in the
				Pharmacovigilance System Master File
				(PSMF) location B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
PRAGIOLA	PRAGIOLA			Pharmacopoeial Certificate of Suitability
CAPSULE,	CAPSULE,			to the relevant Ph. Eur. Monograph -
HARD	HARD		KRKA D.D.	Updated certificate from an already
75MG	75MG	8332/23T, 8333/23T	NOVO MESTO	approved manufacturer
		,		B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
PRAGIOLA	PRAGIOLA			Pharmacopoeial Certificate of Suitability
CAPSULE,	CAPSULE,			to the relevant Ph. Eur. Monograph -
HARD	HARD		KRKA D.D.	Updated certificate from an already
300MG	300MG	8328/23T, 8329/23T	NOVO MESTO	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
1	1			CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active
PRAGIOI A				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European
PRAGIOLA CAPSULE.	PRAGIOLA CAPSULE.			- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability
CAPSULE,	CAPSULE,		KRKA D.D.	- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
		8334/23T, 8335/23T	KRKA D.D. NOVO MESTO	- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already
CAPSULE, HARD	CAPSULE, HARD	8334/23T, 8335/23T		- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
CAPSULE, HARD	CAPSULE, HARD	8334/23T, 8335/23T		- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CAPSULE, HARD	CAPSULE, HARD	8334/23T, 8335/23T		- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY
CAPSULE, HARD	CAPSULE, HARD	8334/23T, 8335/23T		 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
CAPSULE, HARD	CAPSULE, HARD	8334/23T, 8335/23T		 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability for
CAPSULE, HARD	CAPSULE, HARD	8334/23T, 8335/23T		 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability for an active substance For a starting
CAPSULE, HARD	CAPSULE, HARD	8334/23T, 8335/23T		- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in
CAPSULE, HARD	CAPSULE, HARD	8334/23T, 8335/23T		 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active
CAPSULE, HARD 25MG	CAPSULE, HARD 25MG	8334/23T, 8335/23T		 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European
CAPSULE, HARD 25MG PRAGIOLA	CAPSULE, HARD 25MG PRAGIOLA	8334/23T, 8335/23T		 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability
CAPSULE, HARD 25MG PRAGIOLA CAPSULE,	CAPSULE, HARD 25MG PRAGIOLA CAPSULE,	8334/23T, 8335/23T	NOVO MESTO	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD	CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD		NOVO MESTO	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already
CAPSULE, HARD 25MG PRAGIOLA CAPSULE,	CAPSULE, HARD 25MG PRAGIOLA CAPSULE,	8334/23T, 8335/23T 8330/23T, 8331/23T	NOVO MESTO	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD	CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD		NOVO MESTO	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.3.a C.I.3.a - SAFETY, EFFICACY,
CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD	CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD		NOVO MESTO	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD 150MG	CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD 150MG		NOVO MESTO	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD 150MG AUGMENTI	CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD 150MG AUGMENTI		NOVO MESTO KRKA D.D. NOVO MESTO	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD 150MG AUGMENTI N TABLET,	CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD 150MG AUGMENTI N TABLET,		NOVO MESTO KRKA D.D. NOVO MESTO GLAXOSMITH	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product
CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD 150MG AUGMENTI N TABLET, FILM	CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD 150MG AUGMENTI N TABLET, FILM		NOVO MESTO KRKA D.D. NOVO MESTO GLAXOSMITH KLINE	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package
CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD 150MG AUGMENTI N TABLET,	CAPSULE, HARD 25MG PRAGIOLA CAPSULE, HARD 150MG AUGMENTI N TABLET,		NOVO MESTO KRKA D.D. NOVO MESTO GLAXOSMITH	 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product

				procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AUGMENTI N POWDER FOR ORAL SUSPENSI ON (400MG/57 MG)/5ML	AUGMENTI N POWDER FOR ORAL SUSPENSI ON (400MG/57 MG)/5ML	1588/23T	GLAXOSMITH KLINE (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
AUGMENTI N TABLET, FILM COATED 500MG/125 MG	AUGMENTI N TABLET, FILM COATED 500MG/125 MG	1587/23T	GLAXOSMITH KLINE (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 C.I.3.a C.I.3.a - SAFETY, EFFICACY,
AUGMENTI N MIXED FRUIT POWDER FOR ORAL SUSPENSI ON (400MG/57 MG)/5ML	AUGMENTI N MIXED FRUIT POWDER FOR ORAL SUSPENSI ON (400MG/57 MG)/5ML	1589/23T	GLAXOSMITH KLINE (IRELAND) LIMITED	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AUGMENTI N ES POWDER FOR ORAL SUSPENSI ON (600+42.9) MG/5ML	AUGMENTI N ES POWDER FOR ORAL SUSPENSI ON (600+42.9) MG/5ML	1585/23T	GLAXOSMITH KLINE (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/20M G	LIPOCAT TABLET, FILM COATED 10MG/20M G	4332/23T, 4333/23T, 4334/23T	ELPEN PHARMACEU TICAL 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

				aubatanaa Far ar avairiant - Furan
				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.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermediate used in
LIPOCAT TABLET,	LIPOCAT TABLET,			the manufacturing process of the active substance For an excipient - European
FILM	FILM			Pharmacopoeial Certificate of Suitability
COATED 10MG/80M	COATED 10MG/80M	4326/23T, 4327/23T,	ELPEN PHARMACEU	to the relevant Ph. Eur. Monograph - Updated certificate from an already
G	G	4328/23T	TICAL CO INC	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermediate used in
LIPOCAT TABLET,	LIPOCAT TABLET,			the manufacturing process of the active substance For an excipient - European
FILM	FILM			Pharmacopoeial Certificate of Suitability
COATED 10MG/10M	COATED 10MG/10M	4335/23T, 4336/23T,	ELPEN PHARMACEU	to the relevant Ph. Eur. Monograph - Updated certificate from an already
G	G	4337/23T	TICAL CO INC	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
LIPOCAT	LIPOCAT			material/reagent/intermediate used in the manufacturing process of the active
TABLET,	TABLET,			substance For an excipient - European
FILM COATED	FILM COATED		ELPEN	Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
10MG/40M	10MG/40M	4329/23T, 4330/23T,	PHARMACEU	Updated certificate from an already
G FLUDARAB	G FLUDARAB	4331/23T	TICAL CO INC	approved manufacturer
INE	INE			
ACCORD CONCENT	ACCORD CONCENT			
RATE FOR	RATE FOR			B.II.b.2.a B.II.b.2.a - QUALITY
SOLUTION FOR	SOLUTION FOR			CHANGES - FINISHED PRODUCT - Manufacture - Change to importer,
INFUSION	INFUSION		400000	batch release arrangements and quality
AND INJECTION	AND INJECTION		ACCORD HEALTHCARE	control testing of the finished product - Replacement or addition of a site where
25MG/ML	25MG/ML	4354/23T	S.L.U	batch control/testing takes place
				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
SYMBICOR T	SYMBICOR T			quality control testing sites) - The activities for which the
TURBUHAL	TURBUHAL			manufacturer/importer is responsible
ER POWDER	ER POWDER			include batch release A.4 A.4 - ADMINISTRATIVE CHANGES
FOR	FOR			- Change in the name and/or address
INHALATIO N	INHALATIO N			of: a manufacturer (including where relevant quality control testing sites); or
80MCG/4.5	80MCG/4.5	7867/23T, 7868/23T,	ASTRAZENEC	an ASMF holder; or a supplier of the
MCG	MCG	7869/23T	A AB	active substance, starting material,

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				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)
SOFTACO RT EYE DROPS, SOLUTION IN SINGLE- DOSE CONTAINE R 3.35MG/ML	SOFTACO RT EYE DROPS, SOLUTION IN SINGLE- DOSE CONTAINE R 3.35MG/ML	7870/23T	LABORATOIR ES 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
CANDEPR ESS COMP TABLET 16MG/12.5 MG	CANDEPR ESS COMP TABLET 16MG/12.5 MG	9348/23T, 9349/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDEPR ESS COMP TABLET 8MG/12.5M G	CANDEPR ESS COMP TABLET 8MG/12.5M G	9350/23T, 9351/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
MACROGO L 4000 CASEN RECORDA TI POWDER FOR ORAL SOLUTION IN SACHET 10G	MACROGO L 4000 CASEN RECORDA TI 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
SYMBICOR T TURBUHAL ER POWDER FOR INHALATIO N 320MCG/9 MCG	SYMBICOR T TURBUHAL ER POWDER FOR INHALATIO N 320MCG/9 MCG	7871/23T, 7872/23T, 7873/23T	ASTRAZENEC A 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

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				(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
				A.4 A.4 - ADMINISTRATIVE CHANGES
				- Change in the name and/or address
				of: a manufacturer (including where relevant quality control testing sites); or
SYMBICOR	SYMBICOR			an ASMF holder; or a supplier of the
T	Т			active substance, starting material,
TURBUHAL ER	TURBUHAL ER			reagent or intermediate used in the manufacture of the active substance
POWDER	POWDER			(where specified in the technical
FOR	FOR			dossier) where no Ph. Eur. Certificate of
INHALATIO				Suitability is part of the approved
N 160MCG/4.	N 160MCG/4.	7874/23T, 7875/23T,	ASTRAZENEC	dossier; or a manufacturer of a novel excipient (where specified in the
5MCG	5MCG	7876/23T	A AB	technical dossier)
				C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
SETROPAL	SETROPAL			Leaflet of a generic/hybrid/biosimilar medicinal products following
SOLUTION	SOLUTION			assessment of the same change for the
FOR	FOR		CODAL	reference product - Implementation of
INJECTION 250MCG/5	INJECTION 250MCG/5		CODAL- SYNTO	change(s) for which no new additional data is required to be submitted by the
ML	ML	5678/23T	LIMITED	MAH
				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
PENEMER POWDER	PENEMER POWDER			the manufacturing process of the active substance or change in the
FOR	FOR			manufacturer (including where relevant
SOLUTION	SOLUTION			quality control testing sites) of the active
FOR INJECTION	FOR INJECTION			substance, where no Ph. Eur. Certificate of Suitability is part of the approved
/INFUSION	/INFUSION		CODAL-	dossier - Introduction of a manufacturer
500MG/VIA	500MG/VIA		SYNTO	of the active substance supported by an
L	L	8973/23T	LIMITED	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
PENEMER	PENEMER			substance or change in the
POWDER	POWDER			manufacturer (including where relevant
FOR SOLUTION	FOR SOLUTION			quality control testing sites) of the active substance, where no Ph. Eur. Certificate
FOR	FOR			of Suitability is part of the approved
INJECTION	INJECTION		CODAL-	dossier - Introduction of a manufacturer
/INFUSION 1G/VIAL	/INFUSION 1G/VIAL	8972/23T	SYNTO LIMITED	of the active substance supported by an ASMF
16/VIAL	TG/ VIAL	03121231		

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KAPETRAL	KAPETRAL			B.II.c.1.z B.II.c.1.z - QUALITY
TABLET,	TABLET,			CHANGES - FINISHED PRODUCT -
FILM	FILM			Control of excipients - Change in the
COATED	COATED		REMEDICA	specification parameters and/or limits of
150MG	150MG	8586/23T	LTD	an excipient - Other changes
KAPETRAL	KAPETRAL			B.II.c.1.z B.II.c.1.z - QUALITY
TABLET,	TABLET,			CHANGES - FINISHED PRODUCT -
FILM	FILM			Control of excipients - Change in the
COATED	COATED		REMEDICA	specification parameters and/or limits of
500MG	500MG	9595/22T	LTD	an excipient - Other changes
500iviG	5001VIG	8585/23T	LID	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
HALDOL	HALDOL		JANSSEN-	system, changes in QPPV (including
ORAL	ORAL		CILAG	contact details) and/or changes in the
SOLUTION	SOLUTION		INTERNATION	Pharmacovigilance System Master File
2MG/ML	2MG/ML	8675/23T	AL NV	(PSMF) location
			-	A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
				and/or address of a
				manufacturer/importer of the finished
PROLUTEX	PROLUTEX			
				product (including batch release or
SOLUTION	SOLUTION		1504	quality control testing sites) - The
FOR	FOR		IBSA	activities for which the
INJECTION	INJECTION	8404/23T, 8405/23T,	FARMACEUTI	manufacturer/importer is responsible do
25MG	25MG	8406/23T	CI ITALIA SRL	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
SEPTANES	SEPTANES			material/reagent/intermediate used in
				the manufacturing process of the active
SOLUTION	SOLUTION			substance For an excipient - European
FOR	FOR			
	INJECTION			Pharmacopoeial Certificate of Suitability
INJECTION				to the relevant Ph. Eur. Monograph -
(40MG/5MC	(40MG/5MC	0000 /00 .	OFFERENT	Updated certificate from an already
G)/ML	G)/ML	8320/23T	SEPTODONT	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				 Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
SEPTANES	SEPTANES			material/reagent/intermediate used in
TFORTE	TFORTE			the manufacturing process of the active
SOLUTION	SOLUTION			substance For an excipient - European
FOR	FOR			Pharmacopoeial Certificate of Suitability
INJECTION	INJECTION			to the relevant Ph. Eur. Monograph -
(40MG/10M	(40MG/10M			Updated certificate from an already
CG)/ML	CG)/ML	8319/23T	SEPTODONT	approved manufacturer
		0318/231	JEF TODUNT	
				C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
RIVAROXA	RIVAROXA			Leaflet of a generic/hybrid/biosimilar
BAN/RAFA	BAN/RAFA			medicinal products following
RM	RM			assessment of the same change for the
TABLET,	TABLET,			reference product - Implementation of
FILM	FILM			change(s) for which no new additional
COATED	COATED			data is required to be submitted by the
2.5MG	2.5MG	7841/23T	RAFARM S.A.	MAH
2.0.00				

r				
RIVAROXA BAN/RAFA RM TABLET, FILM COATED 15MG AND 20MG	RIVAROXA BAN/RAFA RM 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
RIVAROXA BAN/RAFA RM TABLET, FILM COATED 20MG	RIVAROXA BAN/RAFA RM 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
RIVAROXA BAN/RAFA RM TABLET, FILM COATED 15MG	RIVAROXA BAN/RAFA RM 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
RIVAROXA BAN/RAFA RM TABLET, FILM COATED 10MG	RIVAROXA BAN/RAFA RM 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
SOLIFENA CIN SANDOZ TABLET, FILM COATED 10MG	SOLIFENA CIN 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
SOLIFENA CIN SANDOZ TABLET, FILM COATED 5MG	SOLIFENA CIN 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

				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,
DUODART	DUODART		GLAXOSMITH KLINE TRADING	manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material,
CAPSULE, HARD	CAPSULE, HARD	8475/23T, 8476/23T	SERVICES LIMITED.	reagent or excipient (when mentioned in the dossier)*
IMODIUM PLUS TABLET 2MG/125M	IMODIUM PLUS TABLET 2MG/125M	7214/23T, 7215/23T,	JOHNSON & JOHNSON HELLAS CONSUMER	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
G	G	7216/23T, 7217/23T	AE	authorisation holder A.7 A.7 - ADMINISTRATIVE
ALFUZOSI N	ALFUZOSI N			CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product,
AUROBIND O TABLET,	AUROBIND O TABLET,			packaging site, manufacturer responsible for batch release, site
PROLONG ED- RELEASE	PROLONG ED- RELEASE		AUROBINDO PHARMA (MALTA)	where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the
10MG	10MG	4359/23T	LIMITED	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
TORVACA RD NEO				material/reagent/intermediate used in the manufacturing process of the active
TABLET, FILM	RD NEO TABLET, FILM			substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
COATED 40MG	COATED 40MG	4949/23T	ZENTIVA K.S.	Updated certificate from an already approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
TORVACA RD NEO	TORVACA RD NEO			the manufacturing process of the active substance For an excipient - European
TABLET, FILM COATED	TABLET, FILM COATED			Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already
20MG	20MG	4950/23T	ZENTIVA K.S.	approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
TORVACA RD NEO	TORVACA RD NEO			CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
TABLET, FILM	TABLET, FILM	4951/23T	ZENTIVA K.S.	Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For

	1	1	1	1
COATED	COATED			an active substance For a starting
10MG	10MG			material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
				to the relevant Ph. Eur. Monograph -
				Updated certificate from an already
				approved manufacturer
				C.I.11.z C.I.11.z - SAFETY,
				EFFICACY, PHARMACOVIGILANCE
				CHANGES - HUMAN AND
SOLIFENA	SOLIFENA			VETERINARY MEDICINAL
CIN	CIN			PRODUCTS - Introduction of, or
SANDOZ	SANDOZ			change(s) to, the obligations and
TABLET,	TABLET,			conditions of a marketing authorisation,
FILM	FILM			including the risk management plan -
COATED	COATED		SANDOZ	Other RMP changes (e.g. agreed
10MG	10MG	6173/23T	GMBH	wording + template change)
				C.I.11.z C.I.11.z - SAFETY,
				EFFICACY, PHARMACOVIGILANCE
				CHANGES - HUMAN AND
SOLIFENA	SOLIFENA			VETERINARY MEDICINAL
CIN	CIN			PRODUCTS - Introduction of, or
SANDOZ	SANDOZ			change(s) to, the obligations and
TABLET,	TABLET,			conditions of a marketing authorisation,
FILM	FILM			including the risk management plan -
COATED	COATED		SANDOZ	Other RMP changes (e.g. agreed
5MG	5MG	6174/23T	GMBH	wording + template change)
				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
SERTRALI	SERTRALI			B.II.e.3.a B.II.e.3.a - QUALITY
NE	NE			CHANGES - FINISHED PRODUCT -
ACCORD	ACCORD			Container closure system - Change in
TABLET,	TABLET,			test procedure for the immediate
FILM	FILM		ACCORD	packaging of the finished product -
COATED	COATED		HEALTHCARE	Minor changes to an approved test
50MG	50MG	7918/23T, 7919/23T	S.L.U	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
SERTRALI	SERTRALI			B.II.e.3.a B.II.e.3.a - QUALITY
NE	NE			CHANGES - FINISHED PRODUCT -
				Container closure system - Change in
TABLET,	TABLET,			test procedure for the immediate
FILM COATED	FILM COATED			packaging of the finished product -
		7016/22T 7017/22T	HEALTHCARE	Minor changes to an approved test
100MG	100MG	7916/23T, 7917/23T	S.L.U	procedure A.5.b A.5.b - ADMINISTRATIVE
SEDTRALL	SEDTRALL			CHANGES - Change in the name
SERTRALI	SERTRALI			and/or address of a
NE	NE			manufacturer/importer of the finished
ACCORD	ACCORD			product (including batch release or
TABLET,	TABLET,		400000	quality control testing sites) - The
FILM	FILM		ACCORD	activities for which the
	COATED	1	HEALTHCARE	manufacturer/importer is responsible do
COATED 50MG	50MG	7068/23T	S.L.U	not include batch release

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SERTRALI NE ACCORD TABLET, FILM COATED 100MG	SERTRALI NE 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
SERTRALI NE ACCORD TABLET, FILM COATED 50MG	SERTRALI NE 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)
SERTRALI NE ACCORD TABLET, FILM COATED 100MG	SERTRALI NE 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)
SERTRALI NE ACCORD TABLET, FILM COATED 50MG	SERTRALI NE 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 B.III.2.a.1 B.III.2.a.1 - QUALITY
MELOREM TABLET 7.5MG	MELOREM TABLET 7.5MG	9464/23T, 9465/23T, 9466/23T	REMEDICA	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	MELOREM TABLET	9461/23T, 9462/23T,	REMEDICA	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
15MG	15MG	9463/23T	LTD	the dossier)*
SPIRONOL ACTONE ACCORD TABLET, FILM COATED 25MG	SPIRONOL ACTONE 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
SPIRONOL ACTONE ACCORD TABLET, FILM COATED 100MG	SPIRONOL ACTONE 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 SUSPENSI ON	NOPRILAM 250 POWDER FOR ORAL SUSPENSI ON	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.	(250MG/62.			
5MG)/5ML	5MG)/5ML			
NOPRILAM 125 POWDER FOR ORAL SUSPENSI ON (125MG/31. 25MG)5ML	NOPRILAM 125 POWDER FOR ORAL SUSPENSI ON (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)
LENALIDO MIDE NORAMED A CAPSULE, HARD 10MG	LENALIDO MIDE NORAMED A 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
LENALIDO MIDE NORAMED A CAPSULE, HARD 5MG	LENALIDO MIDE NORAMED A 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
LENALIDO MIDE NORAMED A CAPSULE, HARD 15MG	LENALIDO MIDE NORAMED A 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
LENALIDO MIDE NORAMED A CAPSULE, HARD 25MG NOPRILAM	LENALIDO MIDE NORAMED A CAPSULE, HARD 25MG NOPRILAM	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 B.II.d.2.d B.II.d.2.d - QUALITY
NOPRILAM DT TABLET, FILM COATED 1000MG	NOPRILAM DT TABLET, FILM COATED 1000MG	9470/23T, 9471/23T, 9472/23T, 9473/23T	BIAL- PORTELA & CA, SA	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 PHARMACEU TICAL LABORATORI ES 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)
CANDESA RTAN KRKA TABLET 4MG	CANDESA RTAN 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
CANDESA RTAN KRKA TABLET 8MG	CANDESA RTAN 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
CANDESA RTAN KRKA TABLET 32MG	CANDESA RTAN 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
CANDESA RTAN KRKA TABLET 16MG	CANDESA RTAN 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
DIAMICRO N MODIFIED- RELEASE TABLET 30MG	DIAMICRO N MODIFIED- RELEASE TABLET 30MG	10372/20T	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)*

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DIAMICRO N MODIFIED- RELEASE TABLET 30MG	DIAMICRO N MODIFIED- RELEASE TABLET 30MG	5081/21T	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)*
DIAMICRO N MODIFIED- RELEASE TABLET 60MG BUTAMED	DIAMICRO N MODIFIED- RELEASE TABLET 60MG	5082/21T	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)*
SYRUP	BUTAMED SYRUP		SAPIENS PHARMACEU	B.I.z B.I.z - Quality change - Active
7.5MG/5ML NOPRILAM 250 POWDER FOR ORAL SUSPENSI ON (250MG/62. 5MG)/5ML	7.5MG/5ML NOPRILAM 250 POWDER FOR ORAL SUSPENSI ON (250MG/62. 5MG)/5ML	9123/23T 9329/23T, 9330/23T	TICALS LTD BIAL- PORTELA & CA, SA	substance - Other variation B.II.d.2.a B.II.d.2.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 SUSPENSI ON (125MG/31. 25MG)5ML	NOPRILAM 125 POWDER FOR ORAL SUSPENSI ON (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

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				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
				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
CELEBREX	CELEBREX			finished product, packaging site,
CAPSULE,	CAPSULE,	8259/23T, 8260/23T,		manufacturer responsible for batch
HARD 100MG	HARD 100MG	8261/23T, 8262/23T, 8263/23T	VIATRIS HELLAS LTD	release, site where batch control takes place, or supplier of a starting
				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
				substance - The change requires
				assessment of the comparability of a
				biological/immunological active
				biological/immunological active substance B.I.a.2.c B.I.a.2.c - QUALITY
				biological/immunological active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE -
				biological/immunological active substance B.I.a.2.c B.I.a.2.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the
				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 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
				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 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,
				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
				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
				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
ALBUNOR	ALBUNOR			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 -
M 20%	M 20%			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
				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
M 20% SOLUTION FOR INFUSION	M 20% SOLUTION FOR INFUSION	4186/23T, 4187/23T,	OCTAPHARM	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
M 20% SOLUTION FOR INFUSION 200G/L	M 20% SOLUTION FOR INFUSION 200G/L	4186/23T, 4187/23T, 4188/23T	OCTAPHARM A (IP) SPRL	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
M 20% SOLUTION FOR INFUSION	M 20% SOLUTION FOR INFUSION			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

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	OCTAPHARM A (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 or use of a different chemically derived substance in the manufacture of 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 - Minor change in the manufacturing process of the active substance - Minor change 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	OCTAPHARM A (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
				manufacturing process of the active substance - The change refers to a
				biological / immunological substance or
				use of a different chemically derived
				substance in the manufacture of a biological/immunological substance,
				which may have a significant impact on
				the quality, safety and efficacy of the
				medicinal product and is not related to a
				protocol B.I.a.2.a B.I.a.2.a - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
				Manufacture - Changes in the
				manufacturing process of the active
				substance - Minor change in the manufacturing process of the active
				substance
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
IRINOTECA	IRINOTECA			an active substance For a starting
N ACCORD	N ACCORD			material/reagent/intermediate used in
CONCENT RATE FOR	CONCENT RATE FOR			the manufacturing process of the active substance For an excipient - European
SOLUTION	SOLUTION			Pharmacopoeial Certificate of Suitability
FOR	FOR		ACCORD	to the relevant Ph. Eur. Monograph -
INFUSION 20MG/ML	INFUSION 20MG/ML	2002/227 2002/227	HEALTHCARE S.L.U	Updated certificate from an already
2010/0/1012	ZUIVIG/IVIL	3882/23T, 3883/23T	3.L.U	approved manufacturer B.II.d.2.d B.II.d.2.d - QUALITY
				CHANGES - FINISHED PRODUCT -
EZETIMIBE	EZETIMIBE		MYLAN	Control of finished product - Change in
/MYLAN TABLET	/MYLAN TABLET		PHARMACEU TICALS	test procedure for the finished product - Other changes to a test procedure
10MG	10MG	3000/23T	LIMITED	(including replacement or addition)
NEBIDO	NEBIDO			B.II.d.2.d B.II.d.2.d - QUALITY
SOLUTION FOR	SOLUTION FOR			CHANGES - FINISHED PRODUCT - Control of finished product - Change in
INJECTION	INJECTION			test procedure for the finished product -
1000MG/4M	1000MG/4M		BAYER	Other changes to a test procedure
L	L	7770/23T	HELLAS ABEE	(including replacement or addition)
				A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
				and/or address of a
REGAINE	REGAINE			manufacturer/importer of the finished
WOMEN'S	WOMEN'S		JOHNSON &	product (including batch release or
FOAM CUTANEO	FOAM CUTANEO		JOHNSON HELLAS	quality control testing sites) - The activities for which the
US FOAM	US FOAM		CONSUMER	manufacturer/importer is responsible do
5% W/W	5% W/W	8859/23T	AE	not include batch release
				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
PHYSIONE	PHYSIONE			CHANGES - FINISHED PRODUCT -
AL 40	AL 40			Control of finished product - Change in
GLUCOSE SOLUTION	GLUCOSE SOLUTION			test procedure for the finished product - Deletion of a test proc
FOR	FOR			B.II.d.2.d B.II.d.2.d - QUALITY
PERITONE	PERITONE	2690/23T, 2691/23T,		CHANGES - FINISHED PRODUCT -
		2692/23T, 2693/23T,		Control of finished product - Change in
DIALYSIS 2.27 %	DIALYSIS 2.27 %	2694/23T, 2695/23T, 2696/23T, 2696/23T, 2697/23T,		test procedure for the finished product - Other changes to a test
W/V/22.7	W/V/22.7	2698/23T, 2699/23T,	BAXTER	B.III.2.b B.III.2.b - QUALITY CHANGES
MG/ML	MG/ML	2700/23T, 5694/23T	(HELLAS) EPE	- CEP/TSE/MONOGRAPHS - Change

	•	r		
				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
				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 -
PHYSIONE	PHYSIONE			Other changes to a test
AL 40	AL 40			B.III.2.b B.III.2.b - QUALITY CHANGES
GLUCOSE	GLUCOSE			- CEP/TSE/MONOGRAPHS - Change
SOLUTION	SOLUTION			to comply with Ph. Eur. or with a
FOR	FOR	0070/00T 0000/00T		national pharmacopoeia of a Member
PERITONE AL	PERITONE AL	2679/23T, 2680/23T,		State - Change to comply with B.II.d.1.d B.II.d.1.d - QUALITY
		2681/23T, 2682/23T, 2683/23T, 2683/23T, 2684/23T,		CHANGES - FINISHED PRODUCT -
3.86 %	3.86 %	2685/23T, 2686/23T,		Control of finished product - Change in
W/V/38.6	W/V/38.6	2687/23T, 2688/23T,	BAXTER	the specification parameters and/or
MG/ML	MG/ML	2689/23T, 5693/23T	(HELLAS) EPE	limits of the finished produc
				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
DUNCOLOUIT	DUNCIONE			test procedure for the finished product -
PHYSIONE	PHYSIONE			Other changes to a test
AL 40 GLUCOSE	AL 40 GLUCOSE			B.III.2.b B.III.2.b - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Change
SOLUTION	SOLUTION			to comply with Ph. Eur. or with a
FOR	FOR			national pharmacopoeia of a Member
PERITONE	PERITONE	2701/23T, 2702/23T,		State - Change to comply with
AL	AL	2703/23T, 2704/23T,		B.II.d.1.d B.II.d.1.d - QUALITY
DIALYSIS	DIALYSIS	2705/23T, 2706/23T,		CHANGES - FINISHED PRODUCT -
1.36 %	1.36 %	2707/23T, 2708/23T,		Control of finished product - Change in
W/V/13.6	W/V/13.6	2709/23T, 2710/23T,	BAXTER	the specification parameters and/or
MG/ML	MG/ML	2711/23T, 5695/23T	(HELLAS) EPE	limits of the finished produc
				C.I.4 C.I.4 - SAFETY, EFFICACY,
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
ASPIRIN	ASPIRIN			
ASPIRIN TABLET	ASPIRIN TABLET		BAYER	Leaflet due to new quality, preclinical,
		9831/22T	BAYER HELLAS ABEE	

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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

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				Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
				A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
ANASTROZ	ANASTROZ			and/or address of a
OLE	OLE			manufacturer/importer of the finished
ACCORD	ACCORD			product (including batch release or
TABLET, FILM	TABLET, FILM		ACCORD	quality control testing sites) - The activities for which the
COATED	COATED		HEALTHCARE	manufacturer/importer is responsible do
1MG	1MG	8481/23T	S.L.U	not include batch release
TENOVIRA	TENOVIRA			C.I.z C.I.z - SAFETY, EFFICACY,
L TABLET,	L TABLET,			PHARMACOVIGILANCE CHANGES -
FILM COATED	FILM COATED		REMEDICA	HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other
163MG	163MG	4280/23T		variation
TENOVIRA	TENOVIRA	1200/201		C.I.z C.I.z - SAFETY, EFFICACY,
L TABLET,	L TABLET,			PHARMACOVIGILANCE CHANGES -
FILM	FILM			HUMAN AND VETERINARY
COATED	COATED	· · · · · · · · · · · ·	REMEDICA	MEDICINAL PRODUCTS - Other
204MG	204MG	4279/23T	LTD	variation A.7 A.7 - ADMINISTRATIVE
VANCO	VANCO			CHANGES - Deletion of manufacturing
SAPIENS	SAPIENS			sites for an active substance,
POWDER	POWDER			intermediate or finished product,
FOR	FOR			packaging site, manufacturer
SOLUTION	SOLUTION			responsible for batch release, site
FOR	FOR			where batch control takes place, or
INFUSION 500MG/VIA	INFUSION 500MG/VIA		SAPIENS PHARMACEU	supplier of a starting material, reagent or excipient (when mentioned in the
L	L	7138/23T	TICALS LTD	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
TEMELIN	TEMELIN			substance For an excipient - European
TABLET,	TABLET,			Pharmacopoeial Certificate of Suitability
FILM COATED	FILM COATED	5539/23T, 5540/23T,	MEDOCHEMIE	to the relevant Ph. Eur. Monograph - Updated certificate from an already
10MG	10MG	5541/23T, 5542/23T	LTD	approved manufacturer
				A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
				and/or address of a
REGAINE MEN'S	REGAINE MEN'S		JOHNSON &	manufacturer/importer of the finished product (including batch release or
FOAM	FOAM		JOHNSON	quality control testing sites) - The
CUTANEO	CUTANEO		HELLAS	activities for which the
US FOAM	US FOAM		CONSUMER	manufacturer/importer is responsible do
5% W/W	5% W/W	9333/23T	AE	not include batch release
ESOMEPR	ESOMEPR AZOLE			C.I.5.z C.I.5.z - SAFETY, EFFICACY,
AZOLE TAD	TAD			PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
CAPSULE,	CAPSULE,			MEDICINAL PRODUCTS - Change in
GASTRO-	GASTRO-			the legal status of a medicinal product
RESISTAN	RESISTAN		TAD PHARMA	for centrally authorised products - Other
T 20MG	T 20MG	7365/23T	GMBH	
				A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
				and/or address of a
TRIACOR	TRIACOR			manufacturer/importer of the finished
TABLET,	TABLET,			product (including batch release or
PROLONG	PROLONG			quality control testing sites) - The
ED- RELEASE	ED- RELEASE		SANOFI WINTHROP	activities for which the manufacturer/importer is responsible do
SMG/5MG	5MG/5MG	9408/23T	INDUSTRIE.	not include batch release
		5700/201	INDUGTRIE.	101 1101000 001011 1010030

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ABSKEN TABLET, FILM COATED 1MG	ABSKEN TABLET, FILM COATED 1MG	4141/23T	WIN MEDICA PHARMACEU TICAL 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 PHARMACEU TICAL 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
PACLITAXE L ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXE L ACCORD CONCENT RATE 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
CELMANTI N TABLET, FILM COATED 40MG	CELMANTI N 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
CELMANTI N TABLET, FILM COATED 10MG	CELMANTI N TABLET, FILM COATED 10MG	2531/23T	MEDOCHEMIE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product 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
CELMANTI N TABLET, FILM COATED 5MG	CELMANTI N 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
CELMANTI N TABLET, FILM COATED 20MG	CELMANTI N 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

				B.I.b.2.e B.I.b.2.e - QUALITY
ADACEL SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	ADACEL SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	8291/23T	SANOFI PASTEUR.	CHANGES - ACTIVE SUBSTANCE - Control 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 AUROBIND O TABLET, FILM COATED 50MG	LOSARTAN AUROBIND O 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- RESISTAN T 1G	SALOFALK TABLET, GASTRO- RESISTAN T 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*
CLOMENTI N TABLET, FILM COATED 10MG	CLOMENTI N TABLET, FILM COATED 10MG	8412/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CLOMENTI N TABLET, FILM COATED 20MG	CLOMENTI N TABLET, FILM COATED 20MG	8410/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY
CLOMENTI N TABLET, FILM COATED 5MG	CLOMENTI N TABLET, FILM COATED 5MG	8413/23T	DELORBIS PHARMACEU TICALS LTD	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

CLOMENTI N TABLET, FILM	CLOMENTI N TABLET, FILM		DELORBIS	material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
COATED 15MG	COATED 15MG	8411/23T	PHARMACEU TICALS LTD	Updated certificate from an already approved manufacturer C.I.z C.I.z - SAFETY, EFFICACY,
FEMOSTO N TABLET, FILM COATED	FEMOSTO N TABLET, FILM COATED	9120/23T	VIATRIS HEALTHCARE LIMITED.	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
EZETIMIBE +SIMVAST ATIN/MYLA N TABLET 10MG/20M G	EZETIMIBE +SIMVAST ATIN/MYLA N TABLET 10MG/20M G	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 A.5.b A.5.b - ADMINISTRATIVE
EZETIMIBE +SIMVAST ATIN/MYLA N TABLET 10MG/10M G	EZETIMIBE +SIMVAST ATIN/MYLA N TABLET 10MG/10M G	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

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PRESSURI	PRESSURI			and/or address of the marketing
SED INHALATIO	SED INHALATIO			authorisation holder
N,	N,			
SUSPENSI	SUSPENSI			
ON 80MCG/2.2	ON 80MCG/2.2			
5MCG/ACT	5MCG/ACT			
UATION	UATION			
SYMBICOR	SYMBICOR			
T PRESSURI	T PRESSURI			
SED	SED			
INHALATIO	INHALATIO			
N, SUSPENSI	N, SUSPENSI			
ON	ON			A.1 A.1 - ADMINISTRATIVE
160/4.5MC	160/4.5MC			CHANGES - Change in the name
G/ACTUATI	G/ACTUATI		ASTRAZENEC	and/or address of the marketing
ON	ON	7709/23T	A AB	authorisation holder
SYMBICOR T	SYMBICOR T			
TURBUHAL	TURBUHAL			
ER	ER			
POWDER FOR	POWDER FOR			
INHALATIO	INHALATIO			A.1 A.1 - ADMINISTRATIVE
N	N			CHANGES - Change in the name
320MCG/9	320MCG/9	7744/00T	ASTRAZENEC	and/or address of the marketing
MCG SYMBICOR	MCG SYMBICOR	7711/23T	A AB	authorisation holder
	T			
TURBUHAL	TURBUHAL			
ER	ER			
POWDER FOR	POWDER FOR			
INHALATIO	INHALATIO			A.1 A.1 - ADMINISTRATIVE
Ν	N			CHANGES - Change in the name
160MCG/4.	160MCG/4.	7710/00T	ASTRAZENEC	and/or address of the marketing
5MCG	5MCG	7712/23T	A AB	authorisation holder B.I.a.2.a B.I.a.2.a - QUALITY
STOVADIS	STOVADIS			CHANGES - ACTIVE SUBSTANCE -
TABLET,	TABLET,			Manufacture - Changes in the
FILM	FILM			manufacturing process of the active
COATED 6.25MG/5M	COATED 6.25MG/5M		LES LABORATOIR	substance - Minor change in the manufacturing process of the active
G	G	8362/23T	ES SERVIER	substance
				C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
IVIVERZ	IVIVERZ			Leaflet of a generic/hybrid/biosimilar medicinal products following
TABLET,	TABLET,			assessment of the same change for the
FILM	FILM			reference product - Implementation of
COATED	COATED		ACCORD	change(s) for which no new additional
600MG/300 MG	600MG/300 MG	1961/22T	HEALTHCARE S.L.U	data is required to be submitted by the MAH
		1301/221	0.L.U	C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
IVIVERZ	IVIVERZ			MEDICINAL PRODUCTS - Change(s) in the Summary of Product
TABLET,	TABLET,			Characteristics, Labelling or Package
FILM	FILM			Leaflet of human medicinal products
COATED	COATED		ACCORD	intended to implement the outcome of a
600MG/300	600MG/300		HEALTHCARE S.L.U	procedure concerning PSUR or PASS, or the outcome of the assessment done
MG	MG	9274/23T		

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				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 EFFERVES CENT TABLET 500MG	PANADOL SOLUBLE EFFERVES CENT 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
DEXAMET HASONE MEDOCHE MIE SOLUTION FOR INJECTION OR INFUSION 4MG/ML	DEXAMET HASONE MEDOCHE MIE 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/VIA L	ZEPILEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	8860/23T	MEDOCHEMIE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
PULMOTO N INHALATIO N POWDER, PRE- DISPENSE D (400+12) MCG/DOSE	PULMOTO N INHALATIO N POWDER, PRE- DISPENSE D (400+12) MCG/DOSE	5720/22T, 5721/22T, 5722/22T, 5723/22T	ELPEN PHARMACEU TICAL 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
PULMOTO N INHALATIO N POWDER, PRE- DISPENSE D (100+6) MCG/DOSE	PULMOTO N INHALATIO N POWDER, PRE- DISPENSE D (100+6) MCG/DOSE	5728/22T, 5729/22T, 5730/22T, 5731/22T	ELPEN PHARMACEU TICAL CO INC	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 B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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
PULMOTO N INHALATIO N POWDER, PRE- DISPENSE D (200+6) MCG/DOSE	PULMOTO N INHALATIO N POWDER, PRE- DISPENSE D (200+6) MCG/DOSE	5724/22T, 5725/22T, 5726/22T, 5727/22T	ELPEN PHARMACEU TICAL 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	VESICARE ORAL		ASTELLAS	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
SUSPENSI	SUSPENSI		PHARMACEU	HUMAN AND VETERINARY
ON	ON		TICALS	MEDICINAL PRODUCTS - Other
1MG/ML	1MG/ML	4725/23T	A.E.B.E.	variation
				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
LIPOPEN	LIPOPEN			control testing of the finished product -
TABLET,	TABLET,			Replacement or addition of a
FILM	FILM		ELPEN	manufacturer responsible for
COATED	COATED	6297/23T, 6298/23T,	PHARMACEU	importation and/or batch release -
5MG/10MG	5MG/10MG	6299/23T	TICAL CO INC	Including batch control/testing
				B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT -
				Manufacture - Replacement or addition
				of a manufacturing site for part or all of
				the manufacturing process of the
				finished product - Secondary packaging
				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,
LIPOPEN	LIPOPEN			batch release arrangements and quality
TABLET,	TABLET,			control testing of the finished product -
FILM	FILM			Replacement or addition of a
COATED 40MG/10M	COATED 40MG/10M	6288/23T, 6289/23T,	ELPEN PHARMACEU	manufacturer responsible for importation and/or batch release -
G	G	6290/23T	TICAL CO INC	Including batch control/testing
	-			B.II.b.1.a B.II.b.1.a - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Replacement or addition
				of a manufacturing site for part or all of the manufacturing process of the
				finished product - Secondary packaging
				site
				B.II.b.1.b B.II.b.1.b - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Replacement or addition
				of a manufacturing site for part or all of the manufacturing process of the
				finished product - Primary packaging
LIPOPEN	LIPOPEN			site
TABLET,	TABLET,			B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY
FILM	FILM			CHANGES - FINISHED PRODUCT -
COATED	COATED	6201/22T 6202/22T		Manufacture - Change to importer,
20MG/10M G	20MG/10M G	6291/23T, 6292/23T, 6293/23T	PHARMACEU TICAL CO INC	batch release arrangements and quality control testing of the finished product -
		02001201		some product -

				Replacement or addition of a manufacturer responsible for
				importation and/or batch release - Including batch control/testing
				B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site B.II.b.1.b B.II.b.1.b - QUALITY
				CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site
LIPOPEN TABLET, FILM COATED 10MG/10M G	LIPOPEN TABLET, FILM COATED 10MG/10M G	6294/23T, 6295/23T, 6296/23T	ELPEN PHARMACEU TICAL 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
LIPOPEN TABLET, FILM COATED	LIPOPEN TABLET, FILM COATED		ELPEN PHARMACEU	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product 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
5MG/10MG LIPOPEN TABLET, FILM COATED 10MG/10M G	5MG/10MG LIPOPEN TABLET, FILM COATED 10MG/10M G	1923/23T 1922/23T	ELPEN PHARMACEU TICAL CO INC	assessment C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product 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/10M G	LIPOPEN TABLET, FILM COATED 20MG/10M G	1921/23T	ELPEN PHARMACEU TICAL 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/10M G	LIPOPEN TABLET, FILM COATED 40MG/10M G	1920/23T	ELPEN PHARMACEU TICAL 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

			I	
				outcome of a PRAC signal recommendation: implementation of
				wording agreed by the competent authority that do not require any further
				assessment
				C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
LIPOPEN TABLET,	LIPOPEN TABLET,			MEDICINAL PRODUCTS - Change(s) in the Summary of Product
FILM COATED	FILM COATED		ELPEN PHARMACEU	Characteristics, Labelling or Package
5MG/10MG	5MG/10MG	8517/22T	TICAL CO INC	Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
				C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
TABLET, FILM	TABLET, FILM			MEDICINAL PRODUCTS - Change(s) in the Summary of Product
COATED 20MG/10M	COATED 20MG/10M		ELPEN PHARMACEU	Characteristics, Labelling or Package
G	G	8515/22T	TICAL CO INC	Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
				C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
TABLET, FILM	TABLET, FILM			MEDICINAL PRODUCTS - Change(s) in the Summary of Product
COATED	COATED		ELPEN PHARMACEU	Characteristics, Labelling or Package
40MG/10M G	40MG/10M G	8514/22T	TICAL CO INC	Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
				C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
LIPOPEN	LIPOPEN			HUMAN AND VETERINARY
TABLET, FILM	TABLET, FILM			MEDICINAL PRODUCTS - Change(s) in the Summary of Product
COATED	COATED		ELPEN	Characteristics, Labelling or Package
10MG/10M G	10MG/10M G	8516/22T	PHARMACEU TICAL CO INC	Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
			GLAXOSMITH KLINE	A.5.b A.5.b - ADMINISTRATIVE
			ΚΑΤΑΝΑΛΩΤΙ	CHANGES - Change in the name
			ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ	and/or address of a manufacturer/importer of the finished
ZOVIDUO	ZOVIDUO		ΕΛΛΑΣ ΑΝΩΝΥΜΗ	product (including batch release or quality control testing sites) - The
CREAM	CREAM		ETAIPEIA	activities for which the
(50MG/10M G)/G	(50MG/10M G)/G	8417/23T	(GSK CH ΕΛΛΑΣ ΑΕ)	manufacturer/importer is responsible do not include batch release
, -			GLAXOSMITH	
			ΚLINE ΚΑΤΑΝΑΛΩΤΙ	A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
			ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ	and/or address of a manufacturer/importer of the finished
OTRIVIN	OTRIVIN		ΕΛΛΑΣ	product (including batch release or
ADVANCE NASAL	ADVANCE NASAL		ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ	quality control testing sites) - The activities for which the
SPRAY, SOLUTION	SPRAY, SOLUTION	8416/23T	(GSK CH ΕΛΛΑΣ ΑΕ)	manufacturer/importer is responsible do not include batch release
JOLUTION	JOLUTION	0+10/201		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
			ASPEN PHARMA	B.I.b.1.z B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE -
EMLA	EMLA	7191/23T, 7192/23T,	TRADING	Control of active substance - Change in
CREAM 5%	CREAM 5%	7193/23T, 7194/23T	LIMITED	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
PALIPERID ONE/TEVA PHARMA PROLONG ED RELEASE SUSPENSI ON FOR INJECTION 100MG PALIPERID	PALIPERID ONE/TEVA PHARMA PROLONG ED RELEASE SUSPENSI ON FOR INJECTION 100MG PALIPERID	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
PALIPERID ONE/TEVA PHARMA PROLONG ED RELEASE SUSPENSI ON FOR INJECTION 75MG	ONE/TEVA PHARMA PROLONG ED RELEASE SUSPENSI ON 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
PALIPERID ONE/TEVA PHARMA PROLONG ED RELEASE SUSPENSI ON FOR INJECTION 150MG	PALIPERID ONE/TEVA PHARMA PROLONG ED RELEASE SUSPENSI ON 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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	ZOLOFT TABLET, FILM COATED 50MG ZOLOFT	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 B.I.a.1.a B.I.a.1.a - QUALITY
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 CONCENT RATE FOR SOLUTION FOR INFUSION 5MG/ML	PROGRAF CONCENT RATE FOR SOLUTION FOR INFUSION 5MG/ML	7099/23T	ASTELLAS PHARMACEU TICALS 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, PROLONG ED- RELEASE 100MG	BLOXAZOC TABLET, PROLONG ED- 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, PROLONG ED- RELEASE 25MG	BLOXAZOC TABLET, PROLONG ED- 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, PROLONG ED- RELEASE 200MG	BLOXAZOC TABLET, PROLONG ED- 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, PROLONG ED- RELEASE 50MG	BLOXAZOC TABLET, PROLONG ED- 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 B.II.b.5.z B.II.b.5.z - QUALITY
CLOZAPIN	CLOZAPIN			CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process
E ACCORD	E ACCORD		ACCORD	tests or limits applied during the
TABLET 100MG	TABLET 100MG	5730/23T	HEALTHCARE S.L.U	manufacture of the finished product - Other changes
SIRODROL	SIRODROL	5750/251	0.2.0	A.1 A.1 - ADMINISTRATIVE
ORAL SOLUTION	ORAL SOLUTION			CHANGES - Change in the name and/or address of the marketing
10MG/ML	10MG/ML	8264/23T	VIANEX S.A	authorisation holder
				B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT -
				Manufacture - Change to importer,
ZARATOR	ZARATOR			batch release arrangements and quality control testing of the finished product -
TABLET,	TABLET,			Replacement or addition of a
FILM COATED	FILM COATED		VIATRIS	manufacturer responsible for importation and/or batch release - Not
40MG	40MG	7971/23T	HELLAS LTD	including batch control/testing
				B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT -
				Manufacture - Change to importer,
LIPITOR	LIPITOR			batch release arrangements and quality control testing of the finished product -
TABLET,	TABLET,			Replacement or addition of a
FILM COATED	FILM COATED		VIATRIS	manufacturer responsible for importation and/or batch release - Not
10MG	10MG	7970/23T	HELLAS LTD	including batch control/testing B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change to importer, batch release arrangements and quality
LIPITOR	LIPITOR			control testing of the finished product -
TABLET, FILM	TABLET, FILM			Replacement or addition of a manufacturer responsible for
COATED	COATED		VIATRIS	importation and/or batch release - Not
20MG	20MG	7969/23T	HELLAS LTD	including batch control/testing B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change to importer, batch release arrangements and quality
ZARATOR	ZARATOR			control testing of the finished product -
TABLET, FILM	TABLET, FILM			Replacement or addition of a manufacturer responsible for
COATED	COATED	7070/00T	VIATRIS	importation and/or batch release - Not
10MG	10MG	7973/23T	HELLAS LTD	including batch control/testing B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change to importer, batch release arrangements and quality
ZARATOR TABLET,	ZARATOR TABLET,			control testing of the finished product - Replacement or addition of a
FILM	FILM			manufacturer responsible for
COATED 20MG	COATED 20MG	7972/23T	VIATRIS HELLAS LTD	importation and/or batch release - Not including batch control/testing
2010	2000			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
LIPITOR TABLET,	LIPITOR TABLET,			control testing of the finished product - Replacement or addition of a
FILM	FILM			manufacturer responsible for
COATED 40MG	COATED 40MG	7968/23T	VIATRIS HELLAS LTD	importation and/or batch release - Not including batch control/testing
PRORAMA	PRORAMA		WIN MEDICA	A.2.b A.2.b - ADMINISTRATIVE
CE CAPSULE,	CE CAPSULE,		PHARMACEU TICAL S.A.	CHANGES - Change in the (invented) name of the medicinal product - for
HARD	HARD	2462/23T, 2463/23T	(TRADING AS	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
				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
PRORAMA	PRORAMA		WIN MEDICA PHARMACEU	products for human use* - Introduction of a summary of pharmacovigilance
CE CAPSULE,	CE CAPSULE,		TICAL S.A. (TRADING AS	system, changes in QPPV (including contact details) and/or changes in the
HARD 5MG/5MG	HARD 5MG/5MG	2456/23T, 2457/23T	WIN MEDICA S.A.)	Pharmacovigilance System Master File (PSMF) location A.2.b A.2.b - ADMINISTRATIVE
				CHANGES - Change in the (invented) name of the medicinal product - for
				Nationally Authorised Products C.I.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
PRORAMA CE CAPSULE,	PRORAMA CE CAPSULE,		WIN MEDICA PHARMACEU TICAL S.A.	products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including
HARD 2.5MG/2.5M	HARD 2.5MG/2.5M		(TRADING AS WIN MEDICA	contact details) and/or changes in the Pharmacovigilance System Master File
G	G	2460/23T, 2461/23T	S.A.)	(PSMF) location A.2.b A.2.b - ADMINISTRATIVE
				CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
				C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction
PRORAMA	PRORAMA		WIN MEDICA	of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction
CE CAPSULE,	CE CAPSULE,		PHARMACEU TICAL S.A.	of a summary of pharmacovigilance system, changes in QPPV (including
HARD 10MG/10M	HARD 10MG/10M	o / = o /o o Ŧ _ o / = o /o = =	(TRADING AS WIN MEDICA	contact details) and/or changes in the Pharmacovigilance System Master File
G	G	2452/23T, 2453/23T	S.A.)	(PSMF) location A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented)
				name of the medicinal product - for Nationally Authorised Products
PRORAMA	PRORAMA		WIN MEDICA PHARMACEU	C.I.8.a C.I.8.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
CE CAPSULE, HARD	CE CAPSULE, HARD		TICAL S.A. (TRADING AS WIN MEDICA	HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of
5MG/2.5MG	5MG/2.5MG	2458/23T, 2459/23T	S.A.)	of, of changes to, a summary of pharmacovigilance system for medicinal

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				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
PRORAMA CE CAPSULE, HARD 10MG/5MG	PRORAMA CE CAPSULE, HARD 10MG/5MG	2454/23T, 2455/23T	WIN MEDICA PHARMACEU TICAL 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
HYDROXY CHLOROQ UINE SULFATE ACCORD TABLET, FILM COATED 200MG	HYDROXY CHLOROQ UINE 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
VALSARTA N KRKA TABLET, FILM COATED 160MG	VALSARTA N 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
VALSARTA N KRKA TABLET, FILM COATED 80MG VALSARTA N KRKA TABLET,	VALSARTA N KRKA TABLET, FILM COATED 80MG VALSARTA N KRKA TABLET,	7997/23T	KRKA D.D. NOVO MESTO KRKA D.D.	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

004755	004755			
COATED 160MG	COATED 160MG			of Ph. Eur. certificate of suitability: For
IOUIVIG	TOUIVIG			an active substance For a starting material/reagent/intermediate used in
				the manufacturing process of 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.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
VALSARTA	VALSARTA			the manufacturing process of the active
N KRKA	N KRKA			substance For an excipient - European
TABLET,	TABLET, FILM			Pharmacopoeial Certificate of Suitability
FILM COATED			KRKA D.D.	to the relevant Ph. Eur. Monograph - Updated certificate from an already
320MG	320MG	7995/23T	NOVO MESTO	approved manufacturer
5201010	0201010	1000/201		B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
VALSARTA	VALSARTA			the manufacturing process of the active
N KRKA	N KRKA			substance For an excipient - European
TABLET,	TABLET,			Pharmacopoeial Certificate of Suitability
FILM	FILM			to the relevant Ph. Eur. Monograph -
COATED	COATED		KRKA D.D.	Updated certificate from an already
40MG	40MG	7998/23T	NOVO MESTO	approved manufacturer
				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
OVNITOO AD	OVNITOO AD			manufacturing process of the finished
SYNTOSAR TIN	SYNTOSAR TIN		CODAL	product, including an intermediate used
TABLET	TABLET	8722/23T, 8723/23T,	CODAL- SYNTO	in the manufacture of the finished product - Minor change in the
300MG	300MG	8724/23T, 8725/23T	LIMITED	manufacturing proc
3001010		0127/201,0120/201		B.II.b.1.e B.II.b.1.e - QUALITY
SYNTOSAR	SYNTOSAR			CHANGES - FINISHED PRODUCT -
TIN	TIN		CODAL-	Manufacture - Replacement or addition
TABLET	TABLET	8726/23T, 8727/23T,	SYNTO	of a manufacturing site for part or all of
150MG	150MG	8728/23T, 8729/23T	LIMITED	the manufacturing process of the
ISONG	1001010	01201201,0123/201		I the manufacturing process of the

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				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
ZITHROMA X POWDER FOR ORAL SUSPENSI ON 200MG/5ML	ZITHROMA X POWDER FOR ORAL SUSPENSI ON 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)
CLOMENTI N TABLET, FILM COATED 5MG	CLOMENTI N TABLET, FILM COATED 5MG	8882/23T, 8883/23T, 8884/23T	DELORBIS PHARMACEU TICALS 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
CLOMENTI N TABLET, FILM COATED 20MG	CLOMENTI N TABLET, FILM COATED 20MG	8873/23T, 8874/23T, 8875/23T	DELORBIS PHARMACEU TICALS 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

INTRATEC T SOLUTION FOR INFUSION 100G/L	INTRATEC T 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
HEXARHIN AL PLUS NASAL SPRAY, SOLUTION (1MG/50MG)/ML	HEXARHIN AL 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
CLOMENTI N TABLET, FILM COATED 15MG	CLOMENTI N TABLET, FILM COATED 15MG	8876/23T, 8877/23T, 8878/23T	DELORBIS PHARMACEU TICALS 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
CLOMENTI N TABLET, FILM COATED 10MG	CLOMENTI N TABLET, FILM COATED 10MG	8879/23T, 8880/23T, 8881/23T	DELORBIS PHARMACEU TICALS LTD	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 B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to 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

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INTRATEC T SOLUTION FOR INFUSION 50G/L	INTRATEC T 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 BIOPRODUCT S 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
LAMIVUDIN E/ZIDOVUD INE AUROBIND O TABLET, FILM COATED 150MG/300 MG	LAMIVUDIN E/ZIDOVUD INE AUROBIND O TABLET, FILM COATED 150MG/300 MG	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)*
STEROFUN DIN ISO SOLUTION FOR INFUSION	STEROFUN DIN 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

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				in the last steps of the synthesis and the material is not claimed to be endotoxin free
ONDANSE TRON ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	ONDANSE TRON 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)
PANTOPRA ZOLE AUROBIND O TABLET, GASTRO- RESISTAN T 40MG	PANTOPRA ZOLE AUROBIND O TABLET, GASTRO- RESISTAN T 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) B.III.1.a.3 B.III.1.a.3 - QUALITY
PANTOPRA ZOLE AUROBIND O TABLET, GASTRO-	PANTOPRA ZOLE AUROBIND O 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

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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) B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active substance For an excipient - European
PROCTO-	PROCTO-		RECORDATI	Pharmacopoeial Certificate of Suitability
GLYVENOL RECTAL	GLYVENOL RECTAL		HELLAS PHARMACEU	to the relevant Ph. Eur. Monograph - Updated certificate from an already
CREAM	CREAM	9006/23T	TICALS SA	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in the manufacturing process of the active
				substance For an excipient - European
PROCTO-	PROCTO-		RECORDATI	Pharmacopoeial Certificate of Suitability
GLYVENOL SUPPOSIT	GLYVENOL SUPPOSIT		HELLAS PHARMACEU	to the relevant Ph. Eur. Monograph - Updated certificate from an already
ORY	ORY	9005/23T	TICALS SA	approved manufacturer
AMOXIL	AMOXIL		GLAXOSMITH	B.II.e.5.b B.II.e.5.b - QUALITY CHANGES - FINISHED PRODUCT -
CAPSULE,	CAPSULE,		KLINE	Container closure system - Change in
HARD 500MG	HARD 500MG	8245/23T	(IRELAND) LIMITED	pack size of the finished product - Deletion of pack size(s)
XALATAN	XALATAN			B.II.e.1.z B.II.e.1.z - QUALITY
EYE DROPS,	EYE DROPS,			CHANGES - FINISHED PRODUCT - Container closure system - Change in
SOLUTION	SOLUTION	= 400/00T	VIATRIS	immediate packaging of the finished
50MCG/ML SANDOSTA	50MCG/ML SANDOSTA	5426/23T	HELLAS LTD	product - Other changes
TIN LAR	TIN LAR			A.5.b A.5.b - ADMINISTRATIVE
POWDER AND	POWDER AND			CHANGES - Change in the name and/or address of a
SOLVENT	SOLVENT			manufacturer/importer of the finished
FOR SUSPENSI	FOR SUSPENSI			product (including batch release or quality control testing sites) - The
ON FOR	ON FOR		NOVARTIS	activities for which the
INJECTION 20MG	INJECTION 20MG	6829/23T	IRELAND LIMITED	manufacturer/importer is responsible do not include batch release
SANDOSTA	SANDOSTA			
TIN LAR POWDER	TIN LAR POWDER			A.5.b A.5.b - ADMINISTRATIVE
AND	AND			CHANGES - Change in the name and/or address of a
SOLVENT	SOLVENT			manufacturer/importer of the finished
FOR SUSPENSI	FOR SUSPENSI			product (including batch release or quality control testing sites) - The
ON FOR	ON FOR		NOVARTIS	activities for which the
INJECTION 30MG	INJECTION 30MG	6828/23T	IRELAND LIMITED	manufacturer/importer is responsible do not include batch release
SANDOSTA	SANDOSTA			A.5.b A.5.b - ADMINISTRATIVE
TIN LAR POWDER	TIN LAR POWDER			CHANGES - Change in the name and/or address of a
AND	AND			manufacturer/importer of the finished
SOLVENT FOR	SOLVENT FOR		NOVARTIS IRELAND	product (including batch release or quality control testing sites) - The
SUSPENSI	SUSPENSI	6830/23T	LIMITED	activities for which the

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ON FOR	ON FOR			manufacturer/importer is responsible do
INJECTION 10MG	INJECTION 10MG			not include batch release
FELDENE	FELDENE			
TABLET, DISPERSIB	TABLET, DISPERSIB		PFIZER	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT -
		4604/22T		
LE 20MG	LE 20MG	4694/23T	HELLAS AE	
				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
TETRAXIM	TETRAXIM			of Suitability is part of the approved
SUSPENSI	SUSPENSI			dossier - The proposed manufacturer is
ON FOR	ON FOR			part of the same pharmaceutical group
INJECTION	INJECTION			as the currently approved manufacturer
IN PRE-	IN PRE-			B.I.b.z B.I.b.z - QUALITY CHANGES -
FILLED	FILLED		SANOFI	ACTIVE SUBSTANCE - Control of
SYRINGE	SYRINGE	5614/23T, 5615/23T	PASTEUR.	active substance - Other variation
XEOMIN	XEOMIN			B.II.b.1.a B.II.b.1.a - QUALITY
POWDER	POWDER			CHANGES - FINISHED PRODUCT -
FOR	FOR			Manufacture - Replacement or addition
SOLUTION	SOLUTION			of a manufacturing site for part or all of
FOR	FOR INJECTION		MERZ	the manufacturing process of the
INJECTION		6702/22T	PHARMACEU	finished product - Secondary packaging
100 UNITS	100 UNITS	6783/23T	TICALS GMBH	
XEOMIN POWDER	XEOMIN POWDER			B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT -
FOR	FOR			Manufacture - Replacement or addition
SOLUTION	SOLUTION			of a manufacturing site for part or all of
FOR	FOR		MERZ	the manufacturing process of the
INJECTION	INJECTION		PHARMACEU	finished product - Secondary packaging
200 UNITS	200 UNITS	6782/23T	TICALS GMBH	site
XEOMIN	XEOMIN	0102/201		B.II.b.1.a B.II.b.1.a - QUALITY
POWDER	POWDER			CHANGES - FINISHED PRODUCT -
FOR	FOR			Manufacture - Replacement or addition
SOLUTION	SOLUTION			of a manufacturing site for part or all of
FOR	FOR		MERZ	the manufacturing process of the
INJECTION	INJECTION		PHARMACEU	finished product - Secondary packaging
50 UNITS	50 UNITS	6784/23T	TICALS GMBH	site
				C.I.5.z C.I.5.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change in
TENEREL	TENEREL			the legal status of a medicinal product
TABLET	TABLET		MEDOCHEMIE	for centrally authorised products - Other
1MG	1MG	4474/23T	LTD	variation
VISPRING	VISPRING			
ADVANCE	ADVANCE		JOHNSON &	
EYE	EYE		JOHNSON	A.2.b A.2.b - ADMINISTRATIVE
DROPS,	DROPS,		HELLAS	CHANGES - Change in the (invented)
SOLUTION	SOLUTION		CONSUMER	name of the medicinal product - for
0.5MG/ML	0.5MG/ML	7943/23T	AE	Nationally Authorised Products
				A.7 Deletion of manufacturing sites for
				an active substance, intermediate or
				finished product, packaging site,
VESICARE	VESICARE			manufacturer responsible for batch
TABLET,	TABLET,		ASTELLAS	release, site where batch control takes
	FILM		PHARMACEU	place, or supplier of a starting material,
FILM		1	TICALS	reagent or excipient (when mentioned in
COATED	COATED			
	COATED 10MG	959/20T	A.E.B.E.	the dossier)*
COATED 10MG	10MG	959/20T	ASTELLAS	the dossier)* A.7 Deletion of manufacturing sites for
COATED 10MG VESICARE	10MG VESICARE	959/20T	ASTELLAS PHARMACEU	the dossier)* A.7 Deletion of manufacturing sites for an active substance, intermediate or
COATED 10MG	10MG	959/20T 960/20T	ASTELLAS	the dossier)* A.7 Deletion of manufacturing sites for

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

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				intended to implement the outcome of a procedure concerning PSUR or PASS,
				or the outcome of the assessment done
				by the competent authority under
				Articles 45 or 46 of Regulation
				1901/2006 - Implementation of wording
				agreed by the competent authority
				B.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 -
REMABIRA	REMABIRA			Manufacture - Change in the
T TABLET,	T TABLET,			manufacturer of a starting
FILM	FILM	9018/23T, 9019/23T,		material/reagent/intermediate used in
COATED	COATED	9020/23T, 9021/23T,	REMEDICA	the manufacturing process of the active
500MG	500MG	9022/23T	LTD	substanc
				B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE -
				Manufacture - Change in batch size
				(including batch size ranges) of active
				substance or intermediate used in the
				manufacturing process of the
				B.I.a.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 -
				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 -
REMABIRA	REMABIRA			Manufacture - Change in the
T TABLET, FILM	T TABLET,	0000/007 0004/007		manufacturer of a starting
	I FILM	9023/23T, 9024/23T,	1	material/reagent/intermediate used in
COATED 250MG	COATED 250MG	9025/23T, 9026/23T, 9027/23T	REMEDICA LTD	the manufacturing process of the active substanc

r	1		T	
REMABIRA T TABLET, FILM COATED	REMABIRA T TABLET, FILM COATED	9013/23T, 9014/23T, 9015/23T, 9016/23T, 9015/23T, 9016/23T,	REMEDICA	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, 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 manufacture of a starting material/reagent/intermediate used in the manufacturing process of the active
1000MG	1000MG	9017/23T	LTD	substanc
TEMELOR SOLUTION FOR INJECTION 4MG/ML	TEMELOR SOLUTION FOR INJECTION 4MG/ML	228/23T, 229/23T, 230/23T, 231/23T, 232/23T	MEDOCHEMIE	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 - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits
PACLITAXE L ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXE L ACCORD CONCENT RATE 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)
CANDESA RTAN KRKA TABLET 32MG	CANDESA RTAN 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

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				Leaflet of a generic/hybrid/biosimilar medicinal products following
				assessment of the 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.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
CANDESA	CANDESA			medicinal products following assessment of the same change for the
RTAN	RTAN			reference product - Implementation of
KRKA TABLET	KRKA TABLET		KRKA D.D.	change(s) for which no new additional data is required to be submitted by the
8MG	8MG	3370/23T	NOVO MESTO	MAH
				C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar medicinal products following
CANDESA	CANDESA			assessment of the same change for the
RTAN KRKA	RTAN KRKA			reference product - Implementation of
TABLET	TABLET		KRKA D.D.	change(s) for which no new additional data is required to be submitted by the
16MG	16MG	3369/23T	NOVO MESTO	MAH
				C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
				medicinal products following
CANDESA RTAN	CANDESA RTAN			assessment of the same change for the reference product - Implementation of
KRKA	KRKA			change(s) for which no new additional
TABLET 4MG	TABLET 4MG	3371/23T	KRKA D.D. NOVO MESTO	data is required to be submitted by the MAH
		5571/251		C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar
				medicinal products following
				assessment of the 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
CANDESA	CANDESA			MEDICINAL PRODUCTS - Change(s) in the Summary of Product
RTAN TAD	RTAN TAD			Characteristics, Labelling or Package
TABLET 32MG	TABLET 32MG	3586/23T	TAD PHARMA GMBH	Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
		0000/201		C.I.2.a C.I.2.a - SAFETY, EFFICACY,
CANDESA RTAN TAD	CANDESA RTAN TAD	3587/23T	TAD PHARMA GMBH	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
		5507/251		

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 SUSPENSI ON (400MG/57 MG)/5ML	NOPRILAM DT POWDER FOR ORAL SUSPENSI ON (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)
AZACITIDI NE/SANDO Z POWDER FOR SUSPENSI ON FOR INJECTION 25MG/ML	AZACITIDI NE/SANDO Z POWDER FOR SUSPENSI ON FOR INJECTION 25MG/ML	6989/23T	SANDOZ PHARMACEU TICALS 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
ANAGRELI DE HYDROCH LORIDE CAPSULE, HARD 0.5MG	ANAGRELI DE HYDROCH LORIDE 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
ABIRATER ONE/SAND OZ TABLET, FILM COATED 500MG	ABIRATER ONE/SAND OZ TABLET, FILM COATED 500MG	6990/23T	SANDOZ PHARMACEU TICALS 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
RIVAROXA BAN/RAFA RM TABLET, FILM COATED 10MG	RIVAROXA BAN/RAFA RM 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
RIVAROXA BAN/RAFA	RIVAROXA BAN/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
RIVAROXA BAN/RAFA RM TABLET, FILM COATED 2.5MG	RIVAROXA BAN/RAFA RM 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
RIVAROXA BAN/RAFA RM TABLET, FILM COATED 10MG	RIVAROXA BAN/RAFA RM 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
RIVAROXA BAN/RAFA RM TABLET, FILM COATED 15MG AND 20MG	RIVAROXA BAN/RAFA RM 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
RIVAROXA BAN/RAFA RM TABLET, FILM COATED 20MG	RIVAROXA BAN/RAFA RM 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
AZACITIDI NE/SANDO Z POWDER FOR SUSPENSI ON FOR INJECTION 25MG/ML	AZACITIDI NE/SANDO Z POWDER FOR SUSPENSI ON FOR INJECTION 25MG/ML	562/23T	SANDOZ PHARMACEU TICALS 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
WELLBUTR IN XR MODIFIED- RELEASE TABLET 150MG WELLBUTR IN YR	WELLBUTR IN XR MODIFIED- RELEASE TABLET 150MG WELLBUTR	312/23T	GLAXOSMITH KLINE (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 C.I.3.b C.I.3.b - SAFETY, EFFICACY,
IN XR MODIFIED-	IN XR MODIFIED-	311/23T	GLAXOSMITH KLINE	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
WELLBUTR IN XR MODIFIED-	WELLBUTR IN XR MODIFIED-		GLAXOSMITH	change(s) which require to be further substantiated by new additional data 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
RELEASE TABLET 150MG	RELEASE TABLET 150MG	4748/23T	KLINE (IRELAND) LIMITED	Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
WELLBUTR IN XR MODIFIED- RELEASE TABLET 300MG	WELLBUTR IN XR MODIFIED- RELEASE TABLET 300MG	4747/23T	GLAXOSMITH KLINE (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 PHARMACEU TICALS 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/VIA L	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIA L	8218/23T, 8219/23T	SAPIENS PHARMACEU TICALS 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 value of DL E - M
				to the relevant Ph. Eur. Monograph New certificate from a new
				manufacturer (replacement or addition)
				B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
VANCO SAPIENS	VANCO SAPIENS			an active substance For a starting material/reagent/intermediate used in
POWDER	POWDER			the manufacturing process of the active
FOR	FOR			substance For an excipient - European
SOLUTION FOR	SOLUTION FOR		SAPIENS	Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph
INFUSION	INFUSION		PHARMACEU	New certificate from a new
1G/VIAL	1G/VIAL	1706/23T	TICALS LTD	manufacturer (replacement or addition)
				B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
VANCO	VANCO			of Ph. Eur. certificate of suitability: For
SAPIENS	SAPIENS			an active substance For a starting material/reagent/intermediate used in
POWDER	POWDER			the manufacturing process of the active
FOR	FOR			substance For an excipient - European
SOLUTION FOR	SOLUTION FOR		SAPIENS	Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph
INFUSION	INFUSION		PHARMACEU	New certificate from a new
1G/VIAL	1G/VIAL	1706/23T	TICALS LTD	manufacturer (replacement or addition) B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
VANCO				Eur. Certificate of suitability or deletion
VANCO SAPIENS	VANCO SAPIENS			of Ph. Eur. certificate of suitability: For an active substance For a starting
POWDER	POWDER			material/reagent/intermediate used in
FOR SOLUTION	FOR SOLUTION			the manufacturing process of the active
FOR	FOR			substance For an excipient - European Pharmacopoeial Certificate of Suitability
INFUSION	INFUSION		SAPIENS	to the relevant Ph. Eur. Monograph
500MG/VIA	500MG/VIA	1705/23T	PHARMACEU TICALS LTD	New certificate from a new manufacturer (replacement or addition)
L	L	1705/251	TICALS LTD	B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
VANCO	VANCO			Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
SAPIENS	SAPIENS			an active substance For a starting
POWDER FOR	POWDER FOR			material/reagent/intermediate used in
SOLUTION	SOLUTION			the manufacturing process of the active substance For an excipient - European
FOR	FOR			Pharmacopoeial Certificate of Suitability
INFUSION	INFUSION		SAPIENS PHARMACEU	to the relevant Ph. Eur. Monograph New certificate from a new
500MG/VIA L	500MG/VIA L	1705/23T	TICALS LTD	manufacturer (replacement or addition)
				C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
VISIOLATA	VISIOLATA			MEDICINAL PRODUCTS - Change(s)
N EYE	N EYE		BAUSCH +	in the Summary of Product
DROPS, SOLUTION	DROPS,		LOMB IRELAND	Characteristics, Labelling or Package
50MCG/ML	SOLUTION 50MCG/ML	1189/22T	LIMITED	Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
			EGIS	C.I.4 C.I.4 - SAFETY, EFFICACY,
			PHARMACEU	PHARMACOVIGILANCE CHANGES -
LIPOCOMB CAPSULE,	LIPOCOMB CAPSULE,		TICALS PRIVATE	HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
HARD	HARD		LIMITED	in the Summary of Product
10MG/10M	10MG/10M	0470/00T 0474/00T	COMPANY	Characteristics, Labelling or Package
G	G	6470/23T, 6471/23T	(EGIS	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/10M G	LIPOCOMB CAPSULE, HARD 20MG/10M G	6468/23T, 6469/23T	EGIS PHARMACEU TICALS 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 SUSPENSI ON 250MG/5ML	CLARIPEN GRANULES FOR ORAL SUSPENSI ON 250MG/5ML	5270/22T, 5271/22T, 5272/22T, 5273/22T, 5274/22T, 5275/22T	ELPEN PHARMACEU TICAL 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

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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
DENTOCAI	DENTOCAI			
NE SOLUTION FOR INJECTION 40MG/0.01 MG/ML	NE 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
DENTOCAI	DENTOCAI			
NE SOLUTION FOR INJECTION 40MG/0.005 MG/ML	NE 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
PNEUMOV	PNEUMOV			
AX 23 SOLUTION FOR INJECTION IN PREFILLED SYRINGE 25MCG/0.5 ML	AX 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 500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION	WILATE 1000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION WILATE 500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION	502/23T, 503/23T, 504/23T	OCTAPHARM A (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 B.II.d.2.c B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Control of 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 reagent or
FOR INJECTION	FOR INJECTION	505/23T, 506/23T, 507/23T	OCTAPHARM A (IP) SPRL	preparation B.I.b.2.d B.I.b.2.d - QUALITY

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				CHANGES - ACTIVE SUBSTANCE - Control 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
				B.II.b.1.f B.II.b.1.f - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Replacement or addition
PENEMER	DENEMED			of a manufacturing site for part or all of
POWDER	PENEMER POWDER			the manufacturing process of the finished product - Site where any
FOR	FOR			manufacturing operation(s) take place,
SOLUTION	SOLUTION			except batch release, batch control, and
FOR	FOR			secondary packaging, for sterile
INJECTION	INJECTION			medicinal products (including those that
/INFUSION 500MG/VIA	/INFUSION 500MG/VIA		CODAL- SYNTO	are aseptically manufactured) excluding biological/ immunological medicinal
L	L	8733/23T	LIMITED	products
				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
PENEMER	PENEMER			finished product - Site where any
POWDER	POWDER			manufacturing operation(s) take place,
FOR	FOR			except batch release, batch control, and
SOLUTION	SOLUTION			secondary packaging, for sterile
FOR INJECTION	FOR INJECTION		CODAL-	medicinal products (including those that are aseptically manufactured) excluding
/INFUSION	/INFUSION		SYNTO	biological/ immunological medicinal
1G/VIAL	1G/VIAL	8732/23T	LIMITED	products
				C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
FELDENE	FELDENE			in the Summary of Product
TABLET,	TABLET,			Characteristics, Labelling or Package
DISPERSIB	DISPERSIB		PFIZER	Leaflet due to new quality, preclinical,
LE 20MG	LE 20MG	3189/22T	HELLAS AE	clinical or pharmacovigilance data
TEKTROTY	TEKTROTY			C.z C.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
D KIT FOR	D KIT FOR			Other variation
RADIOPHA	RADIOPHA			C.I.z C.I.z - SAFETY, EFFICACY,
RMACEUTI	RMACEUTI		NARODOWE	PHARMACOVIGILANCE CHANGES -
CAL	CAL		CENTRUM	
PREPARAT ION 20MCG	PREPARAT ION 20MCG	7776/23T, 7777/23T	BADAN JADROWYCH	MEDICINAL PRODUCTS - Other variation
	1011201000			C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of product Characteristics, Labelling or Package
				Leaflet intended to implement the
				outcome of a PRAC signal
ACETAZOL	ACETAZOL			recommendation: implementation of
AMIDE TABLET	AMIDE TABLET		REMEDICA	wording agreed by the competent authority that do not require any further
250MG	250MG	8858/23T		assessment

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CARMUSTI NE ACCORD POWDER & SOLVENT FOR CONCENT RATE FOR SOL.FOR INF. 100MG	CARMUSTI NE ACCORD POWDER & SOLVENT FOR CONCENT RATE 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	ELIGARD POWDER			
AND SOLVENT FOR SOLUTION FOR INJECTION 22.5MG	AND SOLVENT FOR SOLUTION FOR INJECTION 22.5MG	6729/23T	RECORDATI INDUSTRIA CHIMICA & FARMACEUTI CA 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	ELIGARD POWDER			
AND SOLVENT FOR SOLUTION FOR INJECTION 7.5MG	AND SOLVENT FOR SOLUTION FOR INJECTION 7.5MG	6730/23T	RECORDATI INDUSTRIA CHIMICA & FARMACEUTI CA 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 & FARMACEUTI CA 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
NORDELO Z CONCENT RATE FOR SOLUTION FOR INFUSION 4MG/5ML	NORDELO Z CONCENT RATE 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)*
MEDORPH AN SYRUP 1.5MG/ML	MEDORPH AN SYRUP 1.5MG/ML	5555/23T	MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

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MABRON SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	MABRON SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	8526/23T, 8527/23T	MEDOCHEMIE	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)
ESOMEPR	ESOMEPR	0020/201,0027/201		Certificates exist per material)
AZOLE KRKA GASTRO- RESISTAN T CAPSULE, HARD 20MG	AZOLE KRKA GASTRO- RESISTAN T 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 ROLENIUM	STRABEN LOZENGE 8.75MG ROLENIUM	8458/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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
INHALATIO N POWDER, PRE- DISPENSE D (50+250)M CG/DOSE	INHALATIO N POWDER, PRE- DISPENSE D (50+250)M CG/DOSE	4794/22T	ELPEN PHARMACEU TICAL 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 INHALATIO N POWDER, PRE- DISPENSE D (50+500)M CG/DOSE ROLENIUM	ROLENIUM INHALATIO N POWDER, PRE- DISPENSE D (50+500)M CG/DOSE ROLENIUM	4793/22T	ELPEN PHARMACEU TICAL CO INC ELPEN	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.d B.II.d.2.d - QUALITY
INHALATIO N	INHALATIO N	4795/22T	PHARMACEU TICAL CO INC	CHANGES - FINISHED PRODUCT - Control of finished product - Change in

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POWDER,	POWDER,			test procedure for the finished product -
PRE- DISPENSE	PRE- DISPENSE			Other changes to a test procedure (including replacement or addition)
DISPENSE	DISPENSE			
(50+100)M	(50+100)M			
CG/DOSE	CG/DOSE			
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
RILCAPTO				to the relevant Ph. Eur. Monograph
N TABLET	N TABLET	8000/227	MEDOCHEMIE	New certificate from a new
50MG	50MG	8009/23T	LTD	manufacturer (replacement or addition)
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
RILCAPTO	RILCAPTO			to the relevant Ph. Eur. Monograph
N TABLET	N TABLET		MEDOCHEMIE	New certificate from a new
25MG	25MG	8008/23T	LTD	manufacturer (replacement or addition)
				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 -
ADACEL SUSPENSI	ADACEL SUSPENSI			Substantial change to, or replacement of, a biological/ immunological/
ON FOR	ON FOR			immunochemical test method or a
INJECTION				method using a biological reagent or
IN PRE-	IN PRE-			replacement of a biological reference
FILLED	FILLED		SANOFI	preparation not covered by an approved
SYRINGE	SYRINGE	7318/23T	PASTEUR.	protocol
ABIRATER				
ONE/SAND				B.II.d.2.a B.II.d.2.a - QUALITY
OZ	OZ			CHANGES - FINISHED PRODUCT -
TABLET,	TABLET,			Control of finished product - Change in
FILM	FILM		SANDOZ	test procedure for the finished product -
COATED	COATED		PHARMACEU	Minor changes to an approved test
500MG	500MG	7098/23T	TICALS D.D.	procedure
VAGIFEM	VAGIFEM			B.II.d.2.a B.II.d.2.a - QUALITY
FILM	FILM			CHANGES - FINISHED PRODUCT -
COATED	COATED			Control of finished product - Change in
VAGINAL TABLETS			NOVO	test procedure for the finished product -
10MCG	TABLETS 10MCG	8253/23T	NOVO NORDISK A/S	Minor changes to an approved test procedure
		0200/201		C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar
				medicinal products following
				assessment of the same change for the
NEBIVOLO				reference product - Implementation of
L ACCORD			ACCORD	change(s) for which no new additional
TABLET	TABLET	2331/23T	HEALTHCARE	data is required to be submitted by the
5MG	5MG		S.L.U	MAH

NEBIVOLO L ACCORD TABLET 2.5MG	NEBIVOLO L 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 PHARMACEU TICALS LTD	B.II.e.1.a.2 B.II.e.1.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms B.III.1.b.3 B.III.1.b.3 - QUALITY
HAVRIX ADULTS SUSPENSI ON FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSI ON FOR INJECTION 1440 ELISA UNIT/ML	8105/23T, 8107/23T	GLAXOSMITH KLINE BIOLOGICALS SA	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: 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 SUSPENSI ON FOR INJECTION 720 ELISA UNIT/0.5ML	HAVRIX JUNIOR SUSPENSI ON FOR INJECTION 720 ELISA UNIT/0.5ML	8104/23T, 8106/23T	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
VINBLASTI NE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	VINBLASTI NE 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
LEVOTHYR OXINE ACCORD TABLET 100MCG	LEVOTHYR OXINE 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

				Antiples 45 on 40 of Demulation
				Articles 45 or 46 of Regulation 1901/2006 - Other variation
LEVOTHYR OXINE ACCORD TABLET 25MCG	LEVOTHYR OXINE 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
LEVOTHYR OXINE ACCORD TABLET 50MCG	LEVOTHYR OXINE 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/VIA L	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	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) 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
LAMISIL TABLET 250MG LEXAVON EYE DROPS, SOLUTION 5MG/ML	LAMISIL TABLET 250MG LEXAVON EYE DROPS, SOLUTION 5MG/ML	8746/23T 7652/23T	NOVARTIS IRELAND LIMITED	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.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

SPIRIVA INHALATIO N POWDER, HARD CAPSULE 18MCG	SPIRIVA INHALATIO N POWDER, HARD CAPSULE 18MCG	5955/22T	BOEHRINGER INGELHEIM INTERNATION AL GMBH	C.I. IT.D C.I. IT.D - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - 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
SPIRIVA RESPIMAT SOLUTION FOR INHALATIO N 2.5MCG/PU FF	SPIRIVA RESPIMAT SOLUTION FOR INHALATIO N 2.5MCG/PU FF	5958/22T	BOEHRINGER INGELHEIM INTERNATION AL 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* C.I.11.b C.I.11.b - SAFETY,
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
DUCILTIA GASTRO- RESISTAN T CAPSULE, HARD 30MG	DUCILTIA GASTRO- RESISTAN T CAPSULE, HARD 30MG	1547/23T	PHARMATHE N 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- RESISTAN T CAPSULE, HARD 60MG	DUCILTIA GASTRO- RESISTAN T CAPSULE, HARD 60MG	1546/23T	PHARMATHE N 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
MONTELU KAST ACCORD TABLET, CHEWABL E 4MG	MONTELU KAST ACCORD TABLET, CHEWABL E 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
MONTELU KAST ACCORD TABLET, CHEWABL E 5MG	MONTELU KAST ACCORD TABLET, CHEWABL E 5MG	7880/23T	ACCORD HEALTHCARE S.L.U	the manufacturing process of 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
				material/reagent/intermediate used in

				[
				the MAH where significant assessment by the competent authority is required*
SPIOLTO RESPIMAT SOLUTION FOR INHALATIO N (2.5MCG/2. 5MCG)/DO SE	SPIOLTO RESPIMAT SOLUTION FOR INHALATIO N (2.5MCG/2. 5MCG)/DO SE	5956/22T	BOEHRINGER INGELHEIM INTERNATION AL 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 INHALATIO N	STRIVERDI RESPIMAT SOLUTION FOR INHALATIO N	5954/22T	BOEHRINGER INGELHEIM INTERNATION AL 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 INHALATIO N POWDER, HARD CAPSULE 18MCG	SRIVASSO INHALATIO N POWDER, HARD CAPSULE 18MCG	5957/22T	BOEHRINGER INGELHEIM INTERNATION AL 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 INHALATIO N PRIORIX	YANIMO RESPIMAT SOLUTION FOR INHALATIO N PRIORIX	5953/22T	BOEHRINGER INGELHEIM INTERNATION AL 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*
POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE- FILLED SYRINGE VARILRIX	POWDER & SOLVENT FOR SOL. FOR INJ. IN PRE- FILLED SYRINGE VARILRIX	6075/23T	GLAXOSMITH KLINE 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) B.II.e.3.b B.II.e.3.b - QUALITY
POWDER AND SOLVENT FOR SOLUTION FOR	POWDER AND SOLVENT FOR SOLUTION FOR	6074/23T	GLAXOSMITH KLINE BIOLOGICALS SA	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)

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
TETRA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE- FILLED SYRINGE	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
IDARUBICI N ACCORD SOLUTION FOR INJECTION 5MG/5ML	IDARUBICI N 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)*
IDARUBICI N ACCORD SOLUTION FOR INJECTION 10MG/10ML	IDARUBICI N 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)*
IDARUBICI N ACCORD SOLUTION FOR INJECTION 20MG/20ML	IDARUBICI N 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	PANADOL ADVANCE TABLET, FILM		GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩ ΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ	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
COATED 500MG	COATED 500MG	8620/23T, 8621/23T, 8622/23T, 8623/23T	ΜΟΝΟΠΡΟΣΩ ΠΗ Α.Ε.)	release, site where batch control takes place, or supplier of a starting
LEVETIRA CETAM NORIDEM CONCENT RATE FOR SOLUTION FOR INFUSION 100MG/ML	LEVETIRA CETAM NORIDEM CONCENT RATE FOR SOLUTION FOR INFUSION 100MG/ML	8175/23T	NORIDEM ENTERPRISE S 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 HADJIKYRI AKOS GAS LTD MEDICINAL GAS, LIQUEFIED 100%	MEDICINAL NITROUS OXIDE LINDE HADJIKYRI AKOS GAS LTD MEDICINAL GAS, LIQUEFIED 100%	8753/23T	LINDE HADJIKYRIAK OS 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	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 6000IU LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED	5116/23T, 5117/23T 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 product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability 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

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SYRINGE 10000IU	SYRINGE 10000IU			product - The product is a biological/immunological medicinal
1000010	1000010			product and the change requires an
				assessment of comparability
				B.II.b.3.c B.II.b.3.c - QUALITY CHANGES - FINISHED PRODUCT -
LEDRAXEN	LEDRAXEN			Manufacture - Change in the
SOLUTION	SOLUTION			manufacturing process of the finished
FOR	FOR			product, including an intermediate used
INJECTION IN	INJECTION			in the manufacture of the finished product - The product is a
PREFILLED	PREFILLED			biological/immunological medicinal
SYRINGE	SYRINGE			product and the change requires an
2000IU	2000IU	5110/23T, 5111/23T	VENIPHARM	assessment of comparability
				B.II.b.3.c B.II.b.3.c - QUALITY CHANGES - FINISHED PRODUCT -
LEDRAXEN	LEDRAXEN			Manufacture - Change in the
SOLUTION	SOLUTION			manufacturing process of the finished
FOR INJECTION	FOR INJECTION			product, including an intermediate used in the manufacture of the finished
IN	INJECTION			product - The product is a
PREFILLED	PREFILLED			biological/immunological medicinal
SYRINGE	SYRINGE			product and the change requires an
4000IU	4000IU	5108/23T, 5109/23T	VENIPHARM	assessment of comparability B.II.b.3.c B.II.b.3.c - QUALITY
				CHANGES - FINISHED PRODUCT -
LEDRAXEN	LEDRAXEN			Manufacture - Change in the
SOLUTION	SOLUTION			manufacturing process of the finished
FOR INJECTION	FOR INJECTION			product, including an intermediate used in the manufacture of the finished
IN	IN			product - The product is a
PREFILLED	PREFILLED			biological/immunological medicinal
SYRINGE	SYRINGE	E111/00T E11E/00T		product and the change requires an
8000IU	8000IU	5114/23T, 5115/23T	VENIPHARM	assessment of comparability C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
PRODUOD	PRODUOD			intended to implement the outcome of a
OPA SOLUTION	OPA SOLUTION			procedure concerning PSUR or PASS, or the outcome of the assessment done
FOR	FOR			by the competent authority under
INFUSION	INFUSION		ABBVIE	Articles 45 or 46 of Regulation
(240MG+12 MG)/ML	(240MG+12 MG)/ML	7444/23T	PHARMACEU TICALS S.A.	1901/2006 - Implementation of wording agreed by the competent authority
	NG)/NL	7444/231	TICALS S.A.	B.II.e.2.c B.II.e.2.c - QUALITY
				CHANGES - FINISHED PRODUCT -
				Container closure system - Change in
XYZAL	XYZAL			the specification parameters and/or limits of the immediate packaging of the
ORAL	ORAL			finished product - Deletion of a non-
SOLUTION	SOLUTION		UCB PHARMA	significant specification parameter (e.g.
0.5MG/ML INJEXATE	0.5MG/ML INJEXATE	7799/23T	SA	deletion of an obsolete parameter)
SOLUTION	SOLUTION			
FOR	FOR			B.II.e.7.b B.II.e.7.b - QUALITY
INJECTION	INJECTION			CHANGES - FINISHED PRODUCT -
IN PREFILLED	IN PREFILLED		ACCORD	Container closure system - Change in supplier of packaging components or
SYRINGE	SYRINGE		HEALTHCARE	devices (when mentioned in the dossier)
50MG/ML	50MG/ML	5538/23T	S.L.U	- Replacement or addition of a supplier
				B.I.b.2.a B.I.b.2.a - QUALITY
				CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in
EZETROL	EZETROL			test procedure for active substance or
TABLET	TABLET	7755 (00T	N.V.	starting material/reagent/intermediate
10MG	10MG	7755/23T, 7756/23T	ORGANON	used in the manufacturing process of

				the active substance - 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
INEGY	INEGY			starting material/reagent/intermediate
TABLET	TABLET 10MG/10M		N.V.	used in the manufacturing process of
10MG/10M G	G	7753/23T, 7754/23T	ORGANON	the active substance - 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
INEGY TABLET	INEGY TABLET			starting material/reagent/intermediate used in the manufacturing process of
10MG/20M	10MG/20M		N.V.	the active substance - Minor changes to
G	G	7751/23T, 7752/23T	ORGANON	an approved test procedure
				B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE -
				Control of active substance - Change in
INEGY	INEGY			test procedure for active substance or starting material/reagent/intermediate
TABLET	TABLET			used in the manufacturing process of
10MG/80M	10MG/80M G	7747/00T 7740/00T	N.V. ORGANON	the active substance - Minor changes to
G	G	7747/23T, 7748/23T	ORGANON	an approved test procedure B.I.b.2.a B.I.b.2.a - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
LIPTRUZET TABLET,	LIPTRUZET TABLET,			Control of active substance - Change in test procedure for active substance or
FILM	FILM			starting material/reagent/intermediate
COATED 10MG/40M	COATED 10MG/40M		N.V.	used in the manufacturing process of the active substance - Minor changes to
G	G	7761/23T, 7762/23T	ORGANON	an approved test procedure
				B.I.b.2.a B.I.b.2.a - QUALITY
LIPTRUZET	LIPTRUZET			CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in
TABLET,	TABLET,			test procedure for active substance or
FILM COATED	FILM COATED			starting material/reagent/intermediate used in the manufacturing process of
10MG/80M	10MG/80M		N.V.	the active substance - Minor changes to
G	G	7763/23T, 7764/23T	ORGANON	an approved test procedure
				B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE -
				Control of active substance - Change in
TABLET, FILM	TABLET, FILM			test procedure for active substance or starting material/reagent/intermediate
COATED	COATED			used in the manufacturing process of
10MG/10M G	10MG/10M G	7757/23T, 7758/23T	N.V. ORGANON	the active substance - Minor changes to an approved test procedure
0	0	7737/231, 7730/231	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
INEGY	INEGY			starting material/reagent/intermediate
TABLET 10MG/40M	TABLET 10MG/40M		N.V.	used in the manufacturing process of the active substance - Minor changes to
G	G	7749/23T, 7750/23T	ORGANON	an approved test procedure
				B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE -
LIPTRUZET	LIPTRUZET			Changes - ACTIVE SUBSTANCE - Control of active substance - Change in
TABLET,	TABLET,			test procedure for active substance or
FILM COATED	FILM COATED			starting material/reagent/intermediate used in the manufacturing process of
10MG/20M	10MG/20M		N.V.	the active substance - Minor changes to
G IDARUBICI	G IDARUBICI	7759/23T, 7760/23T	ORGANON	an approved test procedure B.II.e.3.b B.II.e.3.b - QUALITY
N ACCORD	N ACCORD		ACCORD	CHANGES - FINISHED PRODUCT -
SOLUTION	SOLUTION	E007/00T	HEALTHCARE	Container closure system - Change in
FOR	FOR	5027/23T	S.L.U	test procedure for the immediate

F	r	1	r	
INJECTION	INJECTION			packaging of the finished product -
10MG/10ML	10MG/10ML			Other changes to a test procedure
				(including replacement or addition)
				B.II.e.3.b B.II.e.3.b - QUALITY
IDARUBICI	IDARUBICI			CHANGES - FINISHED PRODUCT -
N ACCORD	N ACCORD			Container closure system - Change in
SOLUTION	SOLUTION			test procedure for the immediate
FOR	FOR		ACCORD	packaging of the finished product -
INJECTION	INJECTION	5000 /00 T	HEALTHCARE	Other changes to a test procedure
20MG/20ML	20MG/20ML	5026/23T	S.L.U	(including replacement or addition)
				B.II.e.3.b B.II.e.3.b - QUALITY
IDARUBICI	IDARUBICI			CHANGES - FINISHED PRODUCT -
N ACCORD	N ACCORD			Container closure system - Change in
SOLUTION FOR	SOLUTION FOR		ACCORD	test procedure for the immediate
INJECTION	INJECTION		HEALTHCARE	packaging of the finished product - Other changes to a test procedure
5MG/5ML	5MG/5ML	5028/23T	S.L.U	(including replacement or addition)
LIPTRUZET	LIPTRUZET	5020/231	3.L.U	
TABLET,	TABLET,			
FILM	FILM			
COATED	COATED			
10MG/40M	10MG/40M		N.V.	B.II.z B.II.z - QUALITY CHANGES -
G	G	5281/23T	ORGANON	FINISHED PRODUCT - Other variation
LIPTRUZET	LIPTRUZET			
TABLET,	TABLET,			
FILM	FILM			
COATED	COATED			
10MG/80M	10MG/80M		N.V.	B.II.z B.II.z - QUALITY CHANGES -
G	G	5280/23T	ORGANON	FINISHED PRODUCT - Other variation
LIPTRUZET	LIPTRUZET			
TABLET,	TABLET,			
FILM	FILM			
COATED	COATED			
10MG/20M	10MG/20M		N.V.	B.II.z B.II.z - QUALITY CHANGES -
G	G	5282/23T	ORGANON	FINISHED PRODUCT - Other variation
TABLET, FILM	TABLET, FILM			
10MG/10M	10MG/10M		N.V.	B.II.z B.II.z - QUALITY CHANGES -
G	G	5283/23T	ORGANON	FINISHED PRODUCT - Other variation
<u> </u>		0200/201		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
			JOHNSON &	substance/starting material/reagent/
IMODIUM	IMODIUM		JOHNSON	intermediate/or excipient - New
ORIGINAL	ORIGINAL		HELLAS	certificate for a starting material/reagent/
CAPSULE,	CAPSULE,		CONSUMER	intermediate/or excipient from a new or
HARD 2MG	HARD 2MG	8697/23T	AE	an already approved manufacturer
			UNI-PHARMA	
TREBON-N	TREBON-N		KLEON	
POWDER	POWDER		TSETIS	
FOR ORAL	FOR ORAL		PHARMACEU	
SUSPENSI	SUSPENSI			
ON 200MG/5ML	ON 200MG/5ML	7651/23T	LABORATORI ES SA	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
SPIRIVA	SPIRIVA	1001/201	L0 0A	C.I.z C.I.z - SAFETY, EFFICACY,
INHALATIO	INHALATIO		BOEHRINGER	PHARMACOVIGILANCE CHANGES -
N	N		INGELHEIM	HUMAN AND VETERINARY
POWDER,	POWDER,		INTERNATION	MEDICINAL PRODUCTS - Other
HARD	HARD	6777/22T, 6778/22T	AL GMBH	variation
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CAPSULE 18MCG	CAPSULE 18MCG			B.IV.z B.IV.z - QUALITY CHANGES - Medical Devices - Other variation
SRIVASSO	SRIVASSO			C.I.z C.I.z - SAFETY, EFFICACY,
INHALATIO	INHALATIO			PHARMACOVIGILANCE CHANGES -
N	N			HUMAN AND VETERINARY
POWDER,	POWDER,		BOEHRINGER	MEDICINAL PRODUCTS - Other
HARD	HARD		INGELHEIM	variation
CAPSULE	CAPSULE		INTERNATION	B.IV.z B.IV.z - QUALITY CHANGES -
18MCG	18MCG	6779/22T , 6780/22T	AL GMBH	Medical Devices - Other variation
				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 -
TENODAUN	TENODAW			Manufacture - Change in the
		2060/227 2070/227		manufacturing process of the finishe B.III.1.b.2 B.III.1.b.2 - QUALITY
TABLET, FILM	TABLET, FILM	2969/23T, 2970/23T, 2971/23T, 2972/23T,	ATNAHS PHARMA	CHANGES - CEP/TSE/MONOGRAPHS
COATED	COATED	2973/23T, 2974/23T,	NETHERLAND	- Submission of a new or updated Ph.
50MG	50MG	2975/23T, 2976/23T	S B.V.	Eur. Certificate of suita
			0 2	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
TENORMIN	TENORMIN			B.II.b.3.a B.II.b.3.a - QUALITY
TABLET,	TABLET,	2977/23T, 2978/23T,	ATNAHS	CHANGES - FINISHED PRODUCT -
FILM	FILM	2979/23T, 2980/23T,	PHARMA	Manufacture - Change in the
COATED	COATED	2981/23T, 2982/23T,	NETHERLAND	manufacturing process of the finishe
25MG	25MG	2983/23T, 2984/23T	S B.V.	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 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
TENORMIN	TENORMIN			manufacturing process of the finishe
TABLET,	TABLET,	2961/23T, 2962/23T,	ATNAHS	B.III.1.b.2 B.III.1.b.2 - QUALITY
FILM	FILM	2963/23T, 2964/23T,	PHARMA	CHANGES - CEP/TSE/MONOGRAPHS
COATED	COATED	2965/23T, 2966/23T,	NETHERLAND	- Submission of a new or updated Ph.
100MG	100MG	2967/23T, 2968/23T	S B.V.	Eur. Certificate of suita
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
CEFUROXI				MEDICINAL PRODUCTS - Change(s)
ME VENUS	CEFUROXI ME VENUS			in the Summary of Product Characteristics, Labelling or Package
PHARMA	PHARMA			Leaflet of human medicinal products
POWDER	POWDER			intended to implement the outcome of a
FOR	FOR			procedure concerning PSUR or PASS,
SOLUTION	SOLUTION			or the outcome of the assessment done
FOR	FOR			by the competent authority under
INJECTION	INJECTION		VENUS	Articles 45 or 46 of Regulation
/INFUSION	/INFUSION		PHARMA	1901/2006 - Implementation of wording
1500MG	1500MG	4667/23T	GMBH	agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
CEFUROXI	CEFUROXI			in the Summary of Product
ME VENUS	ME VENUS			Characteristics, Labelling or Package
PHARMA	PHARMA			Leaflet of human medicinal products
POWDER	POWDER			intended to implement the outcome of a
FOR	FOR			procedure concerning PSUR or PASS,
SOLUTION	SOLUTION			or the outcome of the assessment done
FOR	FOR			by the competent authority under
INJECTION	INJECTION		VENUS	Articles 45 or 46 of Regulation
/INFUSION	/INFUSION	4669/22T		1901/2006 - Implementation of wording
750MG ANAFRANI	750MG ANAFRANI	4668/23T	GMBH	agreed by the competent authority A.1 A.1 - ADMINISTRATIVE
L TABLET,	L TABLET,			CHANGES - Change in the name
COATED	COATED		PHARMAAND	and/or address of the marketing
25MG	25MG	8047/23T, 8048/23T	GMBH	authorisation holder
ANAFRANI	ANAFRANI			
L SLOW	L SLOW		PHARMAAND	A.1 A.1 - ADMINISTRATIVE
		0045/00T 0040/00T	GMBH	CHANGES - Change in the name
RELEASE	RELEASE	8045/23T, 8046/23T	GIVIDIT	

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TABLETS DIVIDABLE 75MG	TABLETS DIVIDABLE 75MG			and/or address of the marketing authorisation holder
ANAFRANI L TABLET, COATED 10MG	ANAFRANI L 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
CHORIOM ON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	CHORIOM ON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	8589/23T	IBSA FARMACEUTI CI 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 PROLONG ED RELEASE CAPSULES 37.5MG	EFEXOR XR PROLONG ED 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, PROLONG ED- RELEASE 75MG	EFEXOR XR CAPSULE, HARD, PROLONG ED- 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, PROLONG ED- RELEASE 150MG	EFEXOR XR CAPSULE, HARD, PROLONG ED- 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
ATORVAST ATIN GENERICS TABLET, FILM COATED 20MG	ATORVAST ATIN 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 -

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				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
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate 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 -
ATORVAST	ATORVAST			Control of active substance - Change in
ATIN	ATIN			test procedure for active substance or
GENERICS	GENERICS			starting material/reagent/intermediate
TABLET,	TABLET,		GENERICS	used in the manufacturing process of
FILM	FILM		PHARMA	the active substance - Other changes to
		2005/22T 2006/22T		•
COATED	COATED	3865/23T, 3866/23T,	HELLAS	a test procedure (including replacement
10MG	10MG	3867/23T, 3868/23T	LIMITED	or addition) for the active substance o
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				 Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate 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
ATODUCAT	47001/10-			CHANGES - ACTIVE SUBSTANCE -
ATORVAST	ATORVAST			Control of active substance - Change in
ATIN	ATIN			test procedure for active substance or
GENERICS	GENERICS			starting material/reagent/intermediate
TABLET,	TABLET,		GENERICS	used in the manufacturing process of
FILM	FILM		PHARMA	the active substance - Other changes to
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COATED	COATED	3857/23T, 3858/23T.	HELLAS	a test procedure (including replacement
		3857/23T, 3858/23T, 3859/23T, 3860/23T	HELLAS LIMITED	a test procedure (including replacement or addition) for the active substance o

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ATORVAST ATIN GENERICS TABLET, FILM COATED 10MG	ATORVAST ATIN 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
ATORVAST ATIN GENERICS TABLET, FILM COATED 20MG	ATORVAST ATIN 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
ATORVAST ATIN GENERICS TABLET, FILM COATED 40MG	ATORVAST ATIN 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 LABORATOIR ES 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 C.I.4 C.I.4 - SAFETY, EFFICACY,
COSYREL TABLET, FILM COATED 5MG/5MG	COSYREL TABLET, FILM COATED 5MG/5MG	8789/22T	LES LABORATOIR ES SERVIER	PHARMACOVIGILANCE CHANGES - HUMAN AND 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/10M G	COSYREL TABLET, FILM COATED 10MG/10M G	8792/22T	LES LABORATOIR ES 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 LABORATOIR ES 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

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				Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
DEXAMET HASONE/K ABI SOLUTION FOR INJECTION OR INFUSION 4MG/ML	DEXAMET HASONE/K ABI 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.
				C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
ROSU-ASA CAPSULE, HARD 5MG/100M G	ROSU-ASA CAPSULE, HARD 5MG/100M G	2560/23T	IASIS PHARMACEU 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
ROSU-ASA CAPSULE, HARD	ROSU-ASA CAPSULE, HARD		IASIS PHARMACEU	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package
20MG/100M G	20MG/100M G	2558/23T	TICALS HELLAS SA	Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
ROSU-ASA CAPSULE, HARD 10MG/100M G	ROSU-ASA CAPSULE, HARD 10MG/100M G	2559/23T	IASIS PHARMACEU TICALS 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
ZOLEDRO NIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	ZOLEDRO NIC ACID ALTAN SOLUTION FOR INFUSION 4MG/100ML	8347/23T	ALTAN PHARMACEU TICALS 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/VIA L	PENEMER POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	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
MEDOCIPR IN TABLET, FILM COATED 500MG	MEDOCIPR IN TABLET, FILM COATED 500MG	8575/23T	MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
MEDOCIPR IN TABLET, FILM COATED 250MG	MEDOCIPR IN 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 SPEYWOO D UNITS	AZZALURE POWDER FOR SOLUTION FOR INJECTION 125 SPEYWOO D 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 - Change to in-process tests or limits applied during the manufacture of the active substance - Addition of a new in-process test and limits
REMODULI N SOLUTION FOR INFUSION 2.5MG/ML	REMODULI N SOLUTION FOR INFUSION 2.5MG/ML	5428/23T	FERRER INTERNACION AL 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
REMODULI N SOLUTION FOR INFUSION 10MG/ML REMODULI	REMODULI N SOLUTION FOR INFUSION 10MG/ML REMODULI	5427/23T	FERRER INTERNACION AL 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 B.II.b.3.z B.II.b.3.z - QUALITY
N SOLUTION FOR	N SOLUTION FOR	5430/23T	FERRER INTERNACION AL S.A.	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
REMODULI N SOLUTION FOR INFUSION 1MG/ML	REMODULI N SOLUTION FOR INFUSION 1MG/ML	5429/23T	FERRER INTERNACION AL 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/I NJECTION 1G ADACEL	FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/I NJECTION 1G ADACEL	7795/23T, 7796/23T, 7797/23T, 7798/23T	OCTAPHARM A (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 SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	ADACEL SUSPENSI ON 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

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ARCOXIA TABLET, FILM COATED	ARCOXIA TABLET, FILM COATED	7014/23T, 7015/23T, 7016/23T, 7017/23T,	N.V.	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to 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 manufacture - Replacement or addition of a manufacture - Replacement or addition of a manufacture - Replacement or addition of a manufacturing site for part or all of the manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing site for part or all of the manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging
90MG	90MG	7018/23T	ORGANON	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 site for part or all of the manufacture - Replacement or addition of a manufacturing site for part or all of the manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing site for part or all of the 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 B.I.a.2.a B.I.a.2.a - QUALITY
ALBUREX 20	ALBUREX 20			CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the
SOLUTION	SOLUTION			manufacturing process of the active
FOR INFUSION	FOR INFUSION		CSL BEHRING	substance - Minor change in the manufacturing process of the active
200G/L	200G/L	6959/23T	GMBH	substance
NEFILIN MODIFIED- RELEASE TABLET 6MG/0.4MG	NEFILIN MODIFIED- RELEASE TABLET 6MG/0.4MG	7379/23T, 7380/23T	ELPEN PHARMACEU TICAL 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,	AVELOX TABLET,			
FILM	FILM			A.1 A.1 - ADMINISTRATIVE CHANGES
COATED 400MG	COATED 400MG	6314/23T	BAYER HELLAS ABEE	 Change in the name and/or address of the marketing authorisation holder
CARBOPLA TIN/HOSPI RA SOLUTION FOR INFUSION 10MG/ML	CARBOPLA TIN/HOSPI RA 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	MUNDIPHARM A PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

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OXYNORM SOLUTION FOR INJECTION OR INFUSION 50MG/ML	OXYNORM SOLUTION FOR INJECTION OR INFUSION 50MG/ML	8563/23T	MUNDIPHARM A PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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, CHEWABL E 5MG	MONTOL TABLET, CHEWABL E 5MG	8558/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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, CHEWABL E 4MG	MONTOL TABLET, CHEWABL E 4MG	8559/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
FLEXBUMI N SOLUTION FOR	FLEXBUMI N 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

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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)
				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
FLEXBUMI N	FLEXBUMI N			limits of the finished product - Deletion of a non-significant specification
SOLUTION	SOLUTION		DAVALTA	parameter (e.g. deletion of an obsolete
FOR INFUSION	FOR INFUSION		BAXALTA INNOVATIONS	parameter such as odour and taste or identification test for a colouring or
250G/L	250G/L	7784/23T	GMBH	flavouring material) B.II.d.2.a B.II.d.2.a - QUALITY
				CHANGES - FINISHED PRODUCT -
				Control of finished product - Change in
				test procedure for the finished product - Minor changes to an approved test
				procedure B.I.b.2.a B.I.b.2.a - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
NEPHROT ECT	NEPHROT ECT			Control of active substance - Change in
SOLUTION	SOLUTION		FRESENIUS	test procedure for active substance or starting material/reagent/intermediate
FOR INFUSION	FOR INFUSION		KABI HELLAS SINGLE	used in the manufacturing process of the active substance - Minor changes to
10%	10%	7858/23T, 7859/23T	MEMBER S.A.	an approved test procedure
				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
CREON	CREON			dossier - The change relates to a
10000 CAPSULE,	10000 CAPSULE,		VIATRIS	biological active substance or a starting material/reagent/intermediate used in
HARD	HARD		HEALTHCARE	the manufacture of a
150MG	150MG	3723/23T	LIMITED.	biological/immunological product 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
ODEON				of Suitability is part of the approved
CREON 10000	CREON 10000			dossier - The change relates to a biological active substance or a starting
CAPSULE,	CAPSULE,			material/reagent/intermediate used in the manufacture of a
HARD 150MG	HARD 150MG	3723/23T	HEALTHCARE LIMITED.	biological/immunological product
CREON	CREON			B.I.a.1.e B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE -
20000	20000			Manufacture - Change in the
GASTRO- RESISTAN	GASTRO- RESISTAN			manufacturer of a starting material/reagent/intermediate used in
Т	Т			the manufacturing process of the active
CAPSULE, HARD	CAPSULE, HARD		VIATRIS HEALTHCARE	substance or change in the manufacturer (including where relevant
20000U	20000U	3725/23T	LIMITED.	quality control testing sites) of the active

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				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 historical product
				biological/immunological product 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
CREON	CREON			quality control testing sites) of the active
20000	20000			substance, where no Ph. Eur. Certificate
GASTRO- RESISTAN	GASTRO- RESISTAN			of Suitability is part of the approved dossier - The change relates to a
T	T			biological active substance or a starting
CAPSULE,	CAPSULE,		VIATRIS	material/reagent/intermediate used in
HARD	HARD	0705/007	HEALTHCARE	the manufacture of a
20000U	20000U	3725/23T	LIMITED.	biological/immunological product 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
CREON	CREON			quality control testing sites) of the active
35000	35000			substance, where no Ph. Eur. Certificate
GASTRO- RESISTAN	GASTRO- RESISTAN			of Suitability is part of the approved dossier - The change relates to a
T	T			biological active substance or a starting
CAPSULE,	CAPSULE,		VIATRIS	material/reagent/intermediate used in
HARD	HARD		HEALTHCARE	the manufacture of a
35000U	35000U	3724/23T	LIMITED.	biological/immunological product
				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
CREON	CREON			quality control testing sites) of the active
35000 CASTRO	35000			substance, where no Ph. Eur. Certificate
GASTRO- RESISTAN	GASTRO- RESISTAN			of Suitability is part of the approved dossier - The change relates to a
T	T			biological active substance or a starting
CAPSULE,	CAPSULE,		VIATRIS	material/reagent/intermediate used in
HARD	HARD	2724/22T	HEALTHCARE	the manufacture of a
35000U	35000U	3724/23T	LIMITED.	biological/immunological product B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
DULSEVIA	DULSEVIA			material/reagent/intermediate used in
GASTRO-	GASTRO-			the manufacturing process of the active
RESISTAN	RESISTAN			substance For an excipient - European
	Т			Pharmacopoeial Certificate of Suitability
CAPSULE, HARD	CAPSULE, HARD		TAD PHARMA	to the relevant Ph. Eur. Monograph - Updated certificate from an already
60MG	60MG	7715/23T	GMBH	approved manufacturer
DULSEVIA	DULSEVIA		TAD PHARMA	B.III.1.a.2 B.III.1.a.2 - QUALITY
GASTRO-	GASTRO-	7716/23T	GMBH	CHANGES - CEP/TSE/MONOGRAPHS

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RESISTAN RES	SISTAN			- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
	SULE,			of Ph. Eur. certificate of suitability: For
HARD HAR				an active substance For a starting
30MG 30M	G			material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
				to the relevant Ph. Eur. Monograph -
				Updated certificate from an already
DULSEVIA DUL	SEVIA			approved manufacturer Type IA, B.III.1.a.2 Submission of a new
	SEVIA STRO-			or updated Ph. Eur. certificate of
	SISTAN			suitability
				Suitability
	SULE,			
HARD HAR			TAD PHARMA	
60MG 60M		7720/23T	GMBH	
	SEVIA	1120/231	GIVIDI I	Type IA, B.III.1.a.2 Submission of a new
	STRO-			or updated Ph. Eur. certificate of
	SISTAN			suitability
T T	ISTAN			Suitability
	SULE,			
HARD HAR			TAD PHARMA	
30MG 30M		7721/23T	GMBH	
	ICAGE	1121/201		
-	VDER			B.I.a.2.c - Changes in the
AND AND				manufacturing process of the AS - The
	, VENT			change refers to a [-] substance in the
FOR FOR				manufacture of a
				biological/immunological substance
FOR FOR				which may have a significant impact on
			NOVO	the medicinal product and is not related
1MG 1MG		7403/23T	NORDISK A/S	to a protocol.
	, RDITRO	1403/231	NORDIOR A/O	
PIN PIN				
	XPRO			
	UTION			B.I.a.2.c - Changes in the
FOR FOR				manufacturing process of the AS - The
				change refers to a [-] substance in the
	PRE-			manufacture of a
FILLED FILL				biological/immunological substance
PEN PEN				which may have a significant impact on
	G/1.5M		NOVO	the medicinal product and is not related
L L		7401/23T	NORDISK A/S	to a protocol.
	RDITRO			•
PIN PIN				
FLEXPRO FLEX	XPRO			
	UTION			
FOR FOR				
	CTION			
IN A PRE- IN A	PRE-			
FILLED FILL				A.1 A.1 - ADMINISTRATIVE
PEN PEN				CHANGES - Change in the name
15MG/1.5M 15M	G/1.5M		NOVO	and/or address of the marketing
L L		7402/23T	NORDISK A/S	authorisation holder
	RDITRO			
PIN PIN				
-	XPRO			
	UTION			
FOR FOR				
	CTION			
IN A PRE- IN A				A.1 A.1 - ADMINISTRATIVE
	PRE-			
FILLED FILL	.ED			CHANGES - Change in the name
FILLED FILL PEN PEN	.ED I		NOVO	and/or address of the marketing
FILLEDFILLPENPEN5MG/1.5ML5MG	.ED I G/1.5ML	7400/23T	NORDISK A/S	
FILLEDFILLPENPEN5MG/1.5ML5MGPANADOLPAN	.ED I B/1.5ML IADOL	7400/23T	NORDISK A/S GLAXOSMITH	and/or address of the marketing authorisation holder
FILLEDFILLPENPEN5MG/1.5ML5MGPANADOLPAN	.ED I B/1.5ML IADOL .D AND	7400/23T 3588/23T	NORDISK A/S	and/or address of the marketing

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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 PHARMACEU TICALS 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 PHARMACEU TICALS 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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 LABORATOIR ES 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

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				Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
				agreed by the competent authority
COVERAM TABLET	COVERAM TABLET		LES LABORATOIR	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
10MG/5MG	10MG/5MG	5696/22T	ES SERVIER	agreed by the competent authority C.I.3.a C.I.3.a - SAFETY, EFFICACY,
COVERAM TABLET 5MG/10MG	COVERAM TABLET 5MG/10MG	5695/22T	LES LABORATOIR ES SERVIER	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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/10M G	COVERAM TABLET 10MG/10M G	5697/22T	LES LABORATOIR ES 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 LABORATOIR ES 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
				C.I.3.z C.I.3.z - SAFETY, EFFICACY,
COSYREL TABLET, FILM COATED 5MG/5MG	COSYREL TABLET, FILM COATED 5MG/5MG	7033/21T	LES LABORATOIR ES SERVIER	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a

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				procedure concerning PSUR or PASS, or the outcome of 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 LABORATOIR ES 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/10M G	COVERAM TABLET 10MG/10M G	7038/21T	LES LABORATOIR ES 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 LABORATOIR ES 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 LABORATOIR ES 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

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				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/10M	COSYREL TABLET, FILM COATED 10MG/10M		LES LABORATOIR	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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
G	G	7034/21T	ES SERVIER	
VIACORAM TABLET 7MG/5MG	VIACORAM TABLET 7MG/5MG	7030/21T	LES LABORATOIR ES 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/2.5M G	VIACORAM TABLET 3.5MG/2.5M G	7029/21T	LES LABORATOIR ES 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 LABORATOIR ES 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

PANADOL COLD AND FLU PANADOL COLD AND FLU BIL 2.3 a BILe 3.3 - OUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in test procedure for the immediate packaging of the finished product - BILe 2.2 BILe 2.2 - OUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BILe 2.2 - BILE 2.2 - OUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BILE 2.2 - BILE 2.2 - OUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BILE 2.1 - BILE 2.2 - OUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the inished product - Oualitative and qu BILE 1.2 LIE 1.2 - OUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the finished product - Coulitative and qu BILE 1.2 LIE 1.2 - OUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the finished product - Coulitative and qu BILE 1.2 LIE 1.2 - OUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the manufacturing process of the finished product, function parameters and/or limiter data control the specification parameters and/or limiter data control the specification of manufacturing sites for an active substance. Intermediate used in the manufacturer responsible for batch release, site where batch co			1		
PANADOL COLD AND FLU PANADOL COLD AND FLU PANADOL COLD AND FLU GLAXOSMITH KLINE KATANAQTI KLINE KATANAQTI KLINE COATED GLAXOSMITH 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 - DUALITY 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 - DUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin B.II.e.1.a.1 - 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 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the 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 - Change in the specification parameters and/or limits of the 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 - Change in the manufacturing process of the finished product, function parameters and/or limits of the finished product. CHANGES - FINISHED PRODUCT - CHANGES - FINISHED PRODUCT - CHANGES - FINISHED PRODUCT - CONTED COATED 309/21T, 309/21T, 309/21T, 309/21T, 309/21T, 309/21T, BULIT, a.2 B.II.1.2.2 - QUALITY CHANGES - CEP/TSENTY CHANGES - Deletion of manufacturing sites for an active substance. For a starting material/reagent/intermediate used in the manufacturing process of the finished product, indered product. Catagen finished produci. CHANGES - Deletion of a starting material/reagen/t					1901/2006 - Implementation of wording agreed by the competent authority that
PANADOL COL AND FLU PANADOL COL AND FLU PANADOL COL AND FLU BLIB.2.3 FLISHED SUBJECT BLIB.2.2 FLISHED FLU BLIB.2.2 FLISHED FLU COLALITY CHANGES FLISHED FLU FLISHED FLU FLISHED					require additional minor assessment,
PANADOL COLD AND FLU PANADOL COLD AND FLU S089/21T, 309/21T, 3089/21T, 309/21T, 3089/21T, 309/21T, ANDYTH GLAXOSMITH FLU BILe 2:2 Bille 2:2 CAULITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BILIE 0:2 Bille 2:2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BILIE 1:2 Bille 1:2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BILIE 1:2 Bille 1:2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BILIE 1:2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BILIE 1:2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BILIE 1:2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin limits of the finished produc COLD AND FLU TABLET, FILM COATED FILM COATED S089/21T, 309/21T, 3095/21T, 3096/21T GLAXOSMITH CHANGES - FINISHED PRODUCT - CANTED COATED S089/21T, 309/21T, 3095/21T, 3096/21T AT A - A - ANNINSTRATIVE CHANGES - CPOTES-MONOGRAPHS - SAMAS A: DELORBIS LIPREN TABLET, FLIM LIPREN TABLET, FLIM LIPREN TABLET, FLIM LIPREN TABLET, FLIM					
PANADOL COLD AND FLUPANADOL COLT AND FLUContainer closure system - Change in the specification parameters and/or limits of the immediate packaging 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.z B.II.e.2.c B.II.e.2.c COUALITY 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 the specification parameters and/or limits of the immediate packaging of the finished product - Qualitative and qu B.II.e.1.a.1 B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the finished product - Qualitative and qu B.II.6.1.2 & QUALITY COUDAND FLU TABLET, TABLET, TABLET, COATEDPANADOL COLATEDPANADOL COLATEDCOATED3098/21T, 309/21T, 3098/21T, 3098/21TQUATED3095/21T, 3098/21TCOATED3095/21T, 3098/21TCOATED3095/21T, 3098/21TCOATEDAT A ADMINISTATIVE CHANGES - Change in the grout in intermediate used AT A - ADMINISTATIVE CHANGES - Change in the grout intermediate used, and active substance, or supplier of a starting material, reagent or excipient (when mentioned in the dossior)*LIPREN TABLET, TABLET, TABLET, TABLET, TABLET, FILMLIPREN TABLET, FILMLIPREN TABLET, FILMLIPREN TABLET, FILMLIPREN TABLET, FILMLIPREN TABLET, FILM					
PANADOL COLD AND FLWPANADOL COLD AND FLWPANADOL COLD AND FLWPANADOL COLD AND FLWGLAXOSMTH RANADOL COLD AND FLWBLIR 2.2 BLIR 2.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BLIR 2.2 - SILA 2.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin BLIR 2.2 - SILA 2.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin of the finished product - Quality CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the finished product - Quality CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the finished product COLD AND FLUFLW3089/21T, 3090/21T, 3093/21T, 3099/21T, 3093/21T, 3094/21T, 3095/21T, 3096/21TCHANGES - FINISHED PRODUCT - Control of finished product CHANGES - FINISHED PRODUCT - Control of finished product, induct, inducting in the manufacturing cross of the finished product, inducting in themediate used A 7 A, 7 - ADMINISTRATIVE CHANGES - CANTEDCOATEDCOATED3095/21T, 3096/21TE/VAZ AE)LIPREN TABLET, TABLET, TABLET, TABLET, TABLET, TABLET,LIPREN TABLET, TABLET, TABLET, TABLET, TABLET,LIPREN TABLET, TABLET, TABLET, TABLET, TABLET,LIPREN TABLET, TABLET, TABLET, TABLET,LIPREN TABLET, TABLET, TABLET, TABLET,LIPREN TABLET, TABLET, <td></td> <td></td> <td></td> <td></td> <td></td>					
PANADOL COLD AND FLWPANADOL COLD AND COLD AND COLD AND FLWGLAXOSMITH RUSPETT, 3090/21T, 3095/21T, 3096/21TGLAXOSMITH 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 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packagin glite.1.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Qualitative and qu B.II.6.1.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the finished product - Container closure system - Change in the specification parameters and/or limits of the finished product - Canalier closure system - Change in the specification parameters and/or limits of the finished product - Control of finished product - Control of finished product - Control of finished product - Container closure system - Change in the and/acture process of the finished product, including an intermediate used product, including an intermediate used or excipient (when menioned in the dossier)*LIPREN TABLET, L					
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reference product - Imp	
DEXAMED DEXAMED change(s) for which no	new additional
TABLET TABLET MEDOCHEMIE data is required to be si 0.5MG 0.5MG 6427/23T LTD MAH	ubmitted by the
0.5MG 0.5MG 0427/231 ETD MATT B.II.e.6.a B.II.e.6.a - Q	UALITY
CHANGES - FINISHED	PRODUCT -
ZEPILEN Container closure system POWDER POWDER	
FOR FOR material not in contact v	
SOLUTION SOLUTION product formulation (su	ch as colour of
FOR FOR flip-off caps, colour cod	
INJECTION INJECTION ampoules, change of no /INFUSION /INFUSION MEDOCHEMIE (different plastic used))	- Change that

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ZEPILEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	ZEPILEN POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	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 CONCENT RATE FOR SOLUTION FOR INFUSION 25MG/ML	ACICLOVIR ACCORD CONCENT RATE 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
DUROGESI C PATCH, TRANSDER MAL 100MCG/H	DUROGESI C PATCH, TRANSDER MAL 100MCG/H	2806/23T	JANSSEN- CILAG INTERNATION AL 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
DUROGESI C PATCH, TRANSDER MAL 25MCG/H	DUROGESI C PATCH, TRANSDER MAL 25MCG/H	2808/23T	JANSSEN- CILAG INTERNATION AL 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

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				procedure concerning PSUR or PASS, or the outcome of 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
DUROGESI C PATCH, TRANSDER MAL 50MCG/H	DUROGESI C PATCH, TRANSDER MAL 50MCG/H	2807/23T	JANSSEN- CILAG INTERNATION AL 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 PHARMAS CIENCE TABLET, FILM COATED 80MG	DASATINIB PHARMAS CIENCE TABLET, FILM COATED 80MG	6976/22T, 6977/22T	PHARMASCIE NCE INTERNATION AL 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 PHARMAS CIENCE TABLET, FILM COATED 100MG	DASATINIB PHARMAS CIENCE TABLET, FILM COATED 100MG	6974/22T, 6975/22T	PHARMASCIE NCE INTERNATION AL 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 PHARMAS CIENCE TABLET, FILM COATED 50MG	DASATINIB PHARMAS CIENCE TABLET, FILM COATED 50MG	6980/22T, 6981/22T	PHARMASCIE NCE INTERNATION AL 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 PHARMAS CIENCE TABLET, FILM COATED 140MG	DASATINIB PHARMAS CIENCE TABLET, FILM COATED 140MG	6972/22T, 6973/22T	PHARMASCIE NCE INTERNATION AL 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
				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 -
DASATINIB	DASATINIB			Container closure system - Change in
PHARMAS CIENCE	PHARMAS CIENCE			immediate packaging of the finished product - Change in type of container or
TABLET,	TABLET,		PHARMASCIE	addition of a new container - Deletion of
FILM	FILM		NCE	an immediate packaging container that
COATED 70MG	COATED 70MG	6978/22T, 6979/22T	INTERNATION AL LTD	does not lead to the complete deletion of a strength or pharmaceutical form
	7.0110	0010/221,0010/221		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 -
DASATINIB	DASATINIB			Container closure system - Change in
PHARMAS CIENCE	PHARMAS CIENCE			immediate packaging of the finished product - Change in type of container or
TABLET,	TABLET,		PHARMASCIE	addition of a new container - Deletion of
FILM	FILM		NCE	an immediate packaging container that
COATED 20MG	COATED 20MG	6982/22T, 6983/22T	INTERNATION AL LTD	does not lead to the complete deletion of a strength or pharmaceutical form
DASATINIB	DASATINIB			
PHARMAS	PHARMAS			
CIENCE TABLET,	CIENCE TABLET,		PHARMASCIE	
FILM	FILM		NCE	B.II.d.z B.II.d.z - QUALITY CHANGES -
COATED	COATED		INTERNATION	FINISHED PRODUCT - Control of
80MG DASATINIB	80MG DASATINIB	8159/22T	AL LTD	finished product - Other variation
PHARMAS	PHARMAS			
CIENCE	CIENCE			
TABLET, FILM	TABLET, FILM		PHARMASCIE NCE	B.II.d.z B.II.d.z - QUALITY CHANGES -
COATED	COATED		INTERNATION	FINISHED PRODUCT - Control of
100MG	100MG	8158/22T	AL LTD	finished product - Other variation
DASATINIB PHARMAS	DASATINIB PHARMAS			
CIENCE	CIENCE			
TABLET,	TABLET,		PHARMASCIE	
FILM COATED	FILM COATED		NCE INTERNATION	B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of
50MG	50MG	8161/22T	AL LTD	finished product - Other variation
DASATINIB	DASATINIB			
PHARMAS CIENCE	PHARMAS CIENCE			
TABLET,	TABLET,		PHARMASCIE	
FILM	FILM		NCE	B.II.d.z B.II.d.z - QUALITY CHANGES -
COATED 140MG	COATED 140MG	8157/22T	INTERNATION AL LTD	FINISHED PRODUCT - Control of finished product - Other variation
DASATINIB	DASATINIB			
PHARMAS	PHARMAS			
CIENCE TABLET,	CIENCE TABLET,		PHARMASCIE	
FILM	FILM		NCE	B.II.d.z B.II.d.z - QUALITY CHANGES -
COATED 70MG	COATED 70MG	8160/22T	INTERNATION AL LTD	FINISHED PRODUCT - Control of finished product - Other variation
DASATINIB	DASATINIB	0100/221		
PHARMAS	PHARMAS			
CIENCE TABLET,	CIENCE TABLET,		PHARMASCIE	
FILM	FILM		NCE	B.II.d.z B.II.d.z - QUALITY CHANGES -
COATED	COATED		INTERNATION	FINISHED PRODUCT - Control of
20MG	20MG	8162/22T	AL LTD	finished product - Other variation

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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	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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

CEFUROXI ME-SYNTO POWDER FOR INJECTION 1.5G	CEFUROXI ME-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
CEFUROXI ME-SYNTO POWDER FOR INJECTION 750MG/VIA L	CEFUROXI ME-SYNTO POWDER FOR INJECTION 750MG/VIA L	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	PHARMATHE N 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	PHARMATHE N 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	PHARMATHE N 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	PHARMATHE N 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

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				Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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

APOTEL COLD & FLU DAY & NIGHT EFFERVES	APOTEL COLD & FLU DAY & NIGHT EFFERVES	8026/23T, 8027/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL	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,
TORVACA RD NEO TABLET, FILM COATED 10MG	TORVACA RD 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
TORVACA RD NEO TABLET, FILM COATED 40MG	TORVACA RD NEO TABLET, FILM COATED 40MG	2031/23T, 2032/23T, 2033/23T	ZENTIVA K.S.	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 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
				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

CENT TABLET	CENT TABLET		LABORATORI ES 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
ATORVAST ATIN SANDOZ TABLET, FILM COATED 20MG	ATORVAST ATIN 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
ATORVAST ATIN SANDOZ TABLET, FILM COATED 40MG	ATORVAST ATIN 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
ATORVAST ATIN SANDOZ TABLET, FILM COATED 10MG	ATORVAST ATIN 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
FINASTERI DE ACCORD TABLET, FILM COATED 5MG	FINASTERI DE 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
FINASTERI DE ACCORD TABLET, FILM COATED 1MG	FINASTERI DE 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	DEXATON			A.1 A.1 - ADMINISTRATIVE
ORAL	ORAL			CHANGES - Change in the name
SOLUTION 2MG/5ML	SOLUTION 2MG/5ML	7771/23T	VIANEX S.A	and/or address of the marketing authorisation holder
BOSENTAN	BOSENTAN	7771/201	VIANEA 3.A	
AUROBIND	AUROBIND			
O TABLET,	O TABLET,		AUROBINDO	
FILM	FILM		PHARMA	
COATED	COATED		(MALTA)	B.I.z B.I.z - Quality change - Active
62.5MG	62.5MG	4678/23T	LIMITED	substance - Other variation
BOSENTAN	BOSENTAN			
AUROBIND	AUROBIND			
O TABLET,	O TABLET,		AUROBINDO	
FILM	FILM		PHARMA	
COATED 125MG	COATED 125MG	4677/23T	(MALTA) LIMITED	B.I.z B.I.z - Quality change - Active substance - Other variation
1251010	1251010	4077/231		B.III.1 a) 2. Updated certificate from an
				already approved manufacturer
				B.III.1 b) 3. Updated certificate from an
DELTIUS	DELTIUS	8647/23T, 8648/23T,		already approved manufacturer
CAPSULE,	CAPSULE,	8649/23T, 8650/23T,		B.III.1 b) 4. Deletion of certificates (in
HARD	HARD	8651/23T, 8652/23T,	ITF HELLAS	case multiple certificates exist per
50000IU	50000IU	8653/23T	A.E.	material)
				B.III.1 a) 2. Updated certificate from an
				already approved manufacturer
		0054/00T 0055/00T		B.III.1 b) 3. Updated certificate from an
		8654/23T, 8655/23T,		already approved manufacturer B.III.1 b) 4. Deletion of certificates (in
CAPSULE, HARD	CAPSULE, HARD	8656/23T, 8657/23T, 8658/23T, 8659/23T,	ITF HELLAS	case multiple certificates exist per
25000IU	25000IU	8660/23T	A.E.	material)
2300010	2300010	0000/201	Λ.Ε.	C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
ASPIRIN	ASPIRIN			HUMAN AND VETERINARY
EC	EC			MEDICINAL PRODUCTS - Change(s)
TABLET,	TABLET,			in the Summary of Product
GASTRO-	GASTRO-			Characteristics, Labelling or Package
RESISTAN	RESISTAN		BAYER	Leaflet due to new quality, preclinical,
T 100MG	T 100MG	10245/20T	HELLAS ABEE	clinical or pharmacovigilance data
SPIRIVA	SPIRIVA			B.III.2.b B.III.2.b - QUALITY CHANGES
RESPIMAT SOLUTION	RESPIMAT SOLUTION			- CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a
FOR	FOR			national pharmacopoeia of a Member
INHALATIO	INHALATIO		BOEHRINGER	State - Change to comply with an
N	N		INGELHEIM	update of the relevant monograph of the
2.5MCG/PU	2.5MCG/PU		INTERNATION	Ph. Eur. or national pharmacopoeia of a
FF	FF	7717/23T	AL GMBH	Member State
SPIOLTO	SPIOLTO			
RESPIMAT	RESPIMAT			B.III.2.b B.III.2.b - QUALITY CHANGES
SOLUTION	SOLUTION			- CEP/TSE/MONOGRAPHS - Change
				to comply with Ph. Eur. or with a
INHALATIO N	INHALATIO N		BOEHRINGER	national pharmacopoeia of a Member State - Change to comply with an
(2.5MCG/2.	(2.5MCG/2.		INGELHEIM	update of the relevant monograph of the
5MCG)/DO	5MCG)/DO		INTERNATION	Ph. Eur. or national pharmacopoeia of a
SE	SE	7718/23T	AL GMBH	Member State
				B.III.2.b B.III.2.b - QUALITY CHANGES
				- CEP/TSE/MONOGRAPHS - Change
YANIMO	YANIMO			to comply with Ph. Eur. or with a
RESPIMAT	RESPIMAT			national pharmacopoeia of a Member
SOLUTION	SOLUTION		BOEHRINGER	State - Change to comply with an
FOR				update of the relevant monograph of the
INHALATIO N	INHALATIO N	7719/23T	INTERNATION AL GMBH	Ph. Eur. or national pharmacopoeia of a Member State
		1110/201		C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
TRIATEC	TRIATEC			HUMAN AND VETERINARY
PLUS	PLUS		SANOFI	MEDICINAL PRODUCTS - Change(s)
TABLET	TABLET		WINTHROP	in the Summary of Product
5MG/25MG	5MG/25MG	4882/23T	INDUSTRIE.	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
VINBLASTI NE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/1ML	VINBLASTI NE 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)*
PARACETA MOL ACCORD SOLUTION FOR INFUSION 10MG/ML	PARACETA MOL 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)

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ETOPOSID E ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 20MG/ML	ETOPOSID E ACCORD CONCENT RATE 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 OROMUCO SAL SPRAY, SOLUTION (0.15 + 0.5)% w/v	BENCET MOUTH SPRAY OROMUCO SAL SPRAY, SOLUTION (0.15 + 0.5)% w/v	8485/23T	NASSINGTON	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
SYMBICOR T PRESSURI SED INHALATIO N, SUSPENSI ON 80MCG/2.2 5MCG/ACT UATION	SYMBICOR T PRESSURI SED INHALATIO N, SUSPENSI ON 80MCG/2.2 5MCG/ACT UATION	6868/23T, 6869/23T	ASTRAZENEC A 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
				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 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)
0)//	0/4/5/6655			B.I.a.1.z B.I.a.1.z - QUALITY
SYMBICOR	SYMBICOR			CHANGES - ACTIVE SUBSTANCE -
T PRESSURI	T PRESSURI			Manufacture - Change in the manufacturer of a starting
SED	SED			material/reagent/intermediate used in
INHALATIO	INHALATIO			the manufacturing process of the active
Ν,	N,			substance or change in the
SUSPENSI	SUSPENSI			manufacturer (including where relevant
ON	ON			quality control testing sites) of the active
160/4.5MC	160/4.5MC			substance, where no Ph. Eur. Certificate
G/ACTUATI ON	G/ACTUATI ON	6870/23T, 6871/23T	ASTRAZENEC A AB	of Suitability is part of the approved dossier - Other variation
		0070/231,0071/231	A AD	C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of product
				Characteristics, Labelling or Package
ROSAZIMIB	ROSAZIMIB			Leaflet intended to implement the outcome of a PRAC signal
TABLET,	TABLET,			recommendation: implementation of
FILM	FILM			wording agreed by the competent
COATED	COATED			authority that require additional minor
20MG/10M	20MG/10M		KRKA D.D.	assessment, e.g. translations are not
G	G	2437/23T	NOVO MESTO	yet agreed upon
				C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of product
				Characteristics, Labelling or Package
				Leaflet intended to implement the
				outcome of a PRAC signal recommendation: implementation of
ROSAZIMIB TABLET,	ROSAZIMIB TABLET,			wording agreed by the competent
FILM	FILM			authority that require additional minor
COATED	COATED		KRKA D.D.	assessment, e.g. translations are not
5MG/10MG	5MG/10MG	2436/23T	NOVO MESTO	yet agreed upon
				C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of product
ROSAZIMIB	ROSAZIMIB			Characteristics, Labelling or Package
TABLET,	TABLET,			Leaflet intended to implement the
FILM	FILM			outcome of a PRAC signal
COATED	COATED			recommendation: implementation of
10MG/10M G	10MG/10M G	2438/23T	KRKA D.D. NOVO MESTO	wording agreed by the competent authority that require additional minor
0	9	2430/231		autionity that require additional minor

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				assessment, e.g. translations are not yet agreed upon
LAMISIL ONCE CUTANEO US SOLUTION 1%	LAMISIL ONCE CUTANEO US SOLUTION 1%	8408/23T	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩ ΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩ ΠΗ 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩ ΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩ ΠΗ 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
BIMATOPR OST/PHAR MATHEN EYE DROPS, SOLUTION 0.3MG/ML	BIMATOPR OST/PHAR MATHEN EYE DROPS, SOLUTION 0.3MG/ML	6557/22T	PHARMATHE N S.A.	B.I.z B.I.z - Quality change - Active substance - Other variation
BIMATOPR OST/PHAR MATHEN EYE DROPS, SOLUTION 0.1MG/ML	BIMATOPR OST/PHAR MATHEN EYE DROPS, SOLUTION 0.1MG/ML	6558/22T	PHARMATHE N S.A.	B.I.z B.I.z - Quality change - Active substance - Other variation
MIFLONIDE BREEZHAL ER INHALATIO N POWDER IN CAPSULES 200MCG	MIFLONIDE BREEZHAL ER INHALATIO N 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 BREEZHAL ER INHALATIO N POWDER IN CAPSULES 400MCG	MIFLONIDE BREEZHAL ER INHALATIO N 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/B AXTER(VIA FLO) SOLUTION FOR INFUSION	RINGER LACTATE/B AXTER(VIA FLO) 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	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/VIA L	PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	7252/23T, 7253/23T, 7254/23T, 7255/23T, 7256/23T, 7257/23T, 7258/23T, 7259/23T, 7260/23T	MEDOCHEMIE	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

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				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	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/1M L(0.005% W/V)	LATAZ EYE DROPS, SOLUTION 50MCG/1M L(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 ENTERPRISE S 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 B.II.f.1.d B.II.f.1.d - QUALITY
ZITAMIN SOLUTION FOR	ZITAMIN SOLUTION FOR	1784/23T, 1785/23T	NORIDEM ENTERPRISE S LTD	CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished

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INJECTION 7.5MG/ML	INJECTION 7.5MG/ML			product - Change in storage conditions of the finished product or the
	1.00000000			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
				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
ZITAMIN SOLUTION	ZITAMIN SOLUTION			the specification parameters and/or limits of the finished product - Addition
FOR	FOR		NORIDEM	of a new specification parameter to the
INJECTION	INJECTION		ENTERPRISE	specification with its corresponding test
10MG/ML	10MG/ML	1782/23T, 1783/23T	SLTD	method 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
ZITAMIN	ZITAMIN			B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT -
SOLUTION	SOLUTION			Control of finished product - Change in
FOR	FOR		NORIDEM	the specification parameters and/or
INJECTION 2MG/ML	INJECTION 2MG/ML	1788/23T, 1789/23T	ENTERPRISE S LTD	limits of the finished product - Addition of a new specification parameter to the
ZIVIG/IVIL	ZIVIG/IVIL	1100/201, 1108/201	5110	

	-			
				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	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/VIA L	PAMECIL POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	7210/23T, 7211/23T	MEDOCHEMIE	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	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 MEDICATE D PLASTER TOBRADEX EYE OINTMENT	RAPYDAN MEDICATE D PLASTER TOBRADEX EYE OINTMENT	8387/23T 7827/23T	EUROCEPT INTERNATION AL B.V 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.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
QUETIAPIN E/GENERIC S TABLET, FILM COATED 25MG	QUETIAPIN E/GENERIC S 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
QUETIAPIN E/GENERIC S TABLET, FILM COATED 100MG	QUETIAPIN E/GENERIC S 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
QUETIAPIN E/GENERIC S TABLET, FILM COATED 200MG	QUETIAPIN E/GENERIC S 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
METHOTR EXATE TABLET, FILM COATED 2.5MG	METHOTR EXATE TABLET, FILM COATED 2.5MG	8348/23T	REMEDICA LTD	A.6 A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code
SITAGLIPTI N/METFOR MIN APC MODIFIED- RELEASE TABLET 50MG/1000 MG SITAGLIPTI N/METFOR MIN APC	SITAGLIPTI N/METFOR MIN APC MODIFIED- RELEASE TABLET 50MG/1000 MG SITAGLIPTI N/METFOR MIN APC	3210/23T, 3211/23T, 3212/23T, 3213/23T, 3214/23T, 3213/23T, 3216/23T, 3215/23T, 3216/23T, 3217/23T, 3218/23T, 3219/23T 3220/23T, 3221/23T, 3222/23T, 3223/23T	APC INSTYTUT SP. Z.O.O. APC INSTYTUT SP	B.II.b.2.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 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 B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer
MIN APC MODIFIED-	MIN APC MODIFIED-	3222/23T, 3223/23T, 3224/23T, 3225/23T,	INSTYTUT SP. Z.O.O.	Manufacture - Change to importer, batch release arrangements and quality

RELEASE	RELEASE	3226/23T, 3227/23T,		control testing of the finished
TABLET	TABLET	3228/23T, 3229/23T		B.II.b.5.e B.II.b.5.e - QUALITY
50MG/500M	50MG/500M			CHANGES - FINISHED PRODUCT -
G	G			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
				B.II.b.2.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 -
SITAGLIPTI	SITAGLIPTI			Manufacture - Change in the batch size
N/METFOR	N/METFOR			(including batch size ranges) of the
MIN APC	MIN APC			finished product - Up to 10-f
MODIFIED-	MODIFIED-	3200/23T, 3201/23T,		B.II.b.1.e B.II.b.1.e - QUALITY
RELEASE	RELEASE	3202/23T, 3203/23T,		CHANGES - FINISHED PRODUCT -
TABLET	TABLET	3204/23T, 3205/23T,	APC	Manufacture - Replacement or addition
100MG/100	100MG/100	3206/23T, 3207/23T,	INSTYTUT SP.	of a manufacturing site for part or all of
0MG	0MG	3208/23T, 3209/23T	Z.O.O.	the manufacturing proces
				B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT -
				Manufacture - Replacement or addition
				of a manufacturing site for part or all of
				the manufacturing 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 -
000	000			Manufacture - Replacement or addition
		7050/00T 7054/00T		of a manufacturing site for part or all of
M TABLET	M TABLET	7850/23T, 7851/23T,	MEDOCHEMIE	the manufacturing process of the
300MG	300MG	7852/23T, 7853/23T	LTD	finished product - Secondary packaging

	r			
				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
				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
CONVERIU M TABLET 150MG	CONVERIU M TABLET 150MG	7854/23T, 7855/23T, 7856/23T, 7857/23T	MEDOCHEMIE	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
REMODULI N SOLUTION FOR INFUSION 1MG/ML	REMODULI N SOLUTION FOR INFUSION 1MG/ML	6335/23T	FERRER INTERNACION AL 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)
REMODULI N SOLUTION FOR INFUSION 2.5MG/ML REMODULI N	REMODULI N SOLUTION FOR INFUSION 2.5MG/ML REMODULI N	6334/23T	FERRER INTERNACION AL S.A. FERRER	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Other RMP changes (e.g. agreed wording + template change) C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE
SOLUTION FOR	SOLUTION FOR	6333/23T	INTERNACION AL S.A.	CHANGES - HUMAN AND VETERINARY MEDICINAL

INFUSION	INFUSION			PRODUCTS - Introduction of, or
10MG/ML	10MG/ML			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)
REMODULI N SOLUTION FOR INFUSION 5MG/ML HEXARHIN AL NASAL SPRAY, SOLUTION	REMODULI N SOLUTION FOR INFUSION 5MG/ML HEXARHIN AL NASAL SPRAY, SOLUTION	6336/23T 7390/23T, 7391/23T,	FERRER INTERNACION AL S.A. JOHNSON & JOHNSON HELLAS CONSUMER	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) A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
1MG/ML	1MG/ML	7392/23T	AE	authorisation holder B.II.b.4.a B.II.b.4.a - QUALITY
OPTODRO P-CO EYE DROPS, SOLUTION (2+0.5)%	OPTODRO P-CO EYE DROPS, SOLUTION (2+0.5)%	8513/23T	RAFARM S.A.	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
EFAVIREN Z AUROBIND O TABLET, FILM COATED 600MG	EFAVIREN Z AUROBIND O 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 (where specified in the technical doss C.I.3.a C.I.3.a - SAFETY, EFFICACY,
SEIZAL TABLET, DISPERSIB LE 200MG	SEIZAL TABLET, DISPERSIB LE 200MG	8342/23T	DELORBIS PHARMACEU TICALS LTD	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS,

r	r	1	r	
				or the outcome of 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, DISPERSIB LE 5MG	SEIZAL TABLET, DISPERSIB LE 5MG	8346/23T	DELORBIS PHARMACEU TICALS 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, DISPERSIB LE 25MG	SEIZAL TABLET, DISPERSIB LE 25MG	8345/23T	DELORBIS PHARMACEU TICALS 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, DISPERSIB LE 50MG	SEIZAL TABLET, DISPERSIB LE 50MG	8344/23T	DELORBIS PHARMACEU TICALS 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, DISPERSIB LE 100MG	SEIZAL TABLET, DISPERSIB LE 100MG	8343/23T	DELORBIS PHARMACEU TICALS 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 PHARMACEU TICALS LTD	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS,

				or the outcome of the assessment done by the competent authority under
				Articles 45 or 46 of Regulation
				1901/2006 - Implementation of wording
				agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of the assessment done
0517.01	051741			by the competent authority under
SEIZAL TABLET	SEIZAL TABLET		DELORBIS PHARMACEU	Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
100MG	100MG	8378/23T	TICALS LTD	agreed by the competent authority
		0010/201		C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS, or the outcome of the assessment done
				by the competent authority under
SEIZAL	SEIZAL		DELORBIS	Articles 45 or 46 of Regulation
TABLET	TABLET		PHARMACEU	1901/2006 - Implementation of wording
50MG	50MG	8379/23T	TICALS LTD	agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of the assessment done
SEIZAL	SEIZAL		DELORBIS	by the competent authority under Articles 45 or 46 of Regulation
TABLET	TABLET		PHARMACEU	1901/2006 - Implementation of wording
200MG	200MG	8377/23T	TICALS LTD	agreed by the competent authority
				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
RAPYDAN	RAPYDAN			CHANGES - CEP/TSE/MONOGRAPHS
MEDICATE	MEDICATE		EUROCEPT	- Submission of a new or updated Ph.
		FEDE/DOT FEDE/DOT		Eur. Certificate of suitability or deletion
PLASTER	PLASTER	5525/23T, 5526/23T	AL B.V	of Ph. Eur. certificate of suitability: For

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				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 ENTERPRISE S LTD	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
EZETIMIBE /SIMVASTA TIN ACCORD TABLET 10MG/20M G	EZETIMIBE /SIMVASTA TIN ACCORD TABLET 10MG/20M G	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 /SIMVASTA TIN ACCORD TABLET 10MG/10M G	EZETIMIBE /SIMVASTA TIN ACCORD TABLET 10MG/10M G	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 ENTERPRISE S LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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
SPIRONOL ACTONE ACCORD TABLET, FILM COATED 25MG	SPIRONOL ACTONE 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

		1		finished preduct Addition (
				finished product - Addition of a new specification parameter to the
				specification with its corresponding test
				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 -
SPIRONOL ACTONE	SPIRONOL ACTONE			Container closure system - Change in the specification parameters and/or
ACCORD	ACCORD			limits of the immediate packaging of the
TABLET,	TABLET,		400000	finished product - Addition of a new
FILM COATED	FILM COATED		ACCORD HEALTHCARE	specification parameter to the specification with its corresponding test
100MG	100MG	7894/23T, 7895/23T	S.L.U	method
				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
PANTOPRA ZOLE	PANTOPRA ZOLE			active substance, intermediate or finished product, packaging site,
AUROBIND	AUROBIND			manufacturer responsible for batch
O TABLET,	O TABLET,		AUROBINDO	release, site where batch control takes
GASTRO- RESISTAN	GASTRO-	2624/22T 2622/22T	PHARMA	place, or supplier of a starting material,
T 20MG	RESISTAN T 20MG	2631/23T, 2632/23T, 2633/23T	(MALTA) LIMITED	reagent or excipient (when mentioned in the dossier)*
				B.II.b.1.a B.II.b.1.a - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Replacement or addition of a manufacturing site for part or all of
				the manufacturing process of the
				finished product - Secondary packaging
				site A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
				and/or address of a
				manufacturer/importer of the 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
PANTOPRA ZOLE	PANTOPRA ZOLE			active substance, intermediate or finished product, packaging site,
AUROBIND	AUROBIND			manufacturer responsible for batch
O TABLET,	O TABLET,		AUROBINDO	release, site where batch control takes
GASTRO-	GASTRO-	2628/22T 2620/22T		place, or supplier of a starting material,
RESISTAN T 40MG	RESISTAN T 40MG	2628/23T, 2629/23T, 2630/23T	(MALTA) LIMITED	reagent or excipient (when mentioned in the dossier)*
1 10000	1 101010	2000/201		

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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 B.II.e.5.a.2 B.II.e.5.a.2 - QUALITY
PLASMA- LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	PLASMA- LYTE 148 (PH 7.4) SOLUTION FOR INFUSION	6722/23T	BAXTER (HELLAS) EPE	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	PHARMATHE N 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	PHARMATHE N 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 - 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
ATANTO CAPSULE, HARD	ATANTO CAPSULE,	1010/00T 1011/00T	PHARMATHE	where no Ph. Eur. Certificate of Suitability covering the retest period is
125MG	HARD 125MG	1313/23T, 1314/23T, 1315/23T	N S.A.	part of the approved dossier - Re-test period/storage period -
				B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Performant or addition
				Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the
LOSARTAN /HYDROCH	LOSARTAN /HYDROCH			finished product - Primary packaging site
LOROTHIA ZIDE KRKA	LOROTHIA ZIDE KRKA			B.II.b.1.a B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT -
TABLET, FILM	TABLET, FILM			Manufacture - Replacement or addition of a manufacturing site for part or all of
COATED 100MG/25M	COATED 100MG/25M		KRKA D.D.	the manufacturing process of the finished product - Secondary packaging
G	G	7601/23T, 7602/23T	NOVO MESTO	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
GABAPENT IN	GABAPENT IN			the manufacturing process of the active substance For an excipient - European
ACCORD CAPSULE,	ACCORD CAPSULE,		ACCORD	Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
HARD 400MG	HARD 400MG	8299/23T	HEALTHCARE S.L.U	Updated certificate from an already approved manufacturer
GABAPENT	GABAPENT			B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
IN ACCORD	IN ACCORD			- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
CAPSULE, HARD	CAPSULE, HARD		ACCORD HEALTHCARE	of Ph. Eur. certificate of suitability: For an active substance For a starting
300MG	300MG	8300/23T	S.L.U	material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already
				approved manufacturer B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active
				substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
				New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin
ADRENALI NE INJECTION	ADRENALI NE INJECTION		NORIDEM ENTERPRISE	free B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial
1MG/ML	1MG/ML	8448/23T, 8449/23T	S LTD	updates to Mod. 3.2.S or the ASMF A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
LIDOCAINE ACCORD SOLUTION	LIDOCAINE ACCORD SOLUTION			and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The
FOR INJECTION 20MG/ML	FOR INJECTION 20MG/ML	7809/23T	ACCORD HEALTHCARE S.L.U	activities for which the manufacturer/importer is responsible do not include batch release
				A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a
LIDOCAINE ACCORD SOLUTION	LIDOCAINE ACCORD SOLUTION			manufacturer/importer of the finished product (including batch release or quality control testing sites) - The
FOR INJECTION 10MG/ML	FOR INJECTION 10MG/ML	7810/23T	ACCORD HEALTHCARE S.L.U	activities for which the manufacturer/importer is responsible do not include batch release
LEVOFLOX ACIN VIOSER	LEVOFLOX ACIN VIOSER			B.II.b.4.b B.II.b.4.b - QUALITY CHANGES - FINISHED PRODUCT -
SOLUTION FOR INFUSION	SOLUTION FOR INFUSION	E 4 40/20T	VIOSER S.A. PARENTERAL SOLUTIONS	Manufacture - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to
5MG/ML GLUCAGE N HYPOKIT	5MG/ML GLUCAGE N HYPOKIT	5443/23T	INDUSTRY	10-fold
POWDER AND SOLVENT	POWDER AND SOLVENT			
FOR SOLUTION FOR	FOR SOLUTION FOR			A.1 A.1 - ADMINISTRATIVE CHANGES
INJECTION 1MG METHOTR	INJECTION 1MG METHOTR	7403/23T	NOVO NORDISK A/S	- Change in the name and/or address of the marketing authorisation holder
EXATE ACCORD SOLUTION	EXATE ACCORD SOLUTION			
FOR INJECTION 25MG/ML	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

BUDENOF ALK UNO GASTRO- RESISTAN T GRANULES	BUDENOF ALK UNO GASTRO- RESISTAN T GRANULES		DR. FALK PHARMA	B.II.b).1. a) Secondary packaging site variation Type IAIN (B.II.b.1.a): to add Logifarma S.r.I, Via Campobello 1, 00071 Pomezia, Italy as an alternative site responsible for secondary
9MG DELTIUS ORAL DROPS SOLUTION 10000IU/ML	9MG DELTIUS ORAL DROPS SOLUTION 10000IU/ML	7579/23T	ITF HELLAS A.E.	packaging of the finished product. B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active 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	5819/22T, 5820/22T 5813/22T, 5814/22T	ITF HELLAS A.E.	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) B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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	5813/221, 5814/221 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

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				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
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				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
DELTIUS	DELTIUS			substance For an excipient - European
ORAL	ORAL			Pharmacopoeial Certificate of Suitability
SOLUTION	SOLUTION			to the relevant Ph. Eur. Monograph -
25000IU/2.5	25000IU/2.5	5047/00T 5040/00T	ITF HELLAS	Updated certificate from an already
ML	ML	5817/22T, 5818/22T	A.E.	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)
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
DELTIUS	DELTIUS			Pharmacopoeial Certificate of Suitability
CAPSULE,	CAPSULE,			to the relevant Ph. Eur. Monograph -
HARD	HARD		ITF HELLAS	Updated certificate from an already
25000IU	25000IU	5815/22T, 5816/22T	A.E.	approved manufacturer
		0010/221, 0010/221	∧.∟.	
DELTIUS	DELTIUS			B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY
ORAL	ORAL	2205/247	ITF HELLAS	CHANGES - FINISHED PRODUCT -
DROPS	DROPS	3265/21T	A.E.	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 PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in

CAPOLEV CAPOLEV DELORBIS DELORBIS Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate of suitability or deletion of Ph. Eur. Certificate of suitability or deletion of Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 4MG 8327/23T DELORBIS PHARMACEU Updated certificate from an already approved manufacturer 4MG 8327/23T TICALS LTD B.III.1.a.2 QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 4MG 8327/23T TICALS LTD B.III.1.a.2 QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active and the manufacturing process of the active and the manufacturing process of the active the manufacture for a starting material/reagent/intermediate used in the manufacturing process of the active				1	
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CAPOLEV TABLET 4MGCAPOLEV TABLETCAPOLEV TABLET 4MGCAPOLEV TABLET AMGDELORBIS PHARMACEU TICALS LTDDELORBIS PHARMACEU TICALS LTDDELORBIS PHARMACEU TICALS LTDDELORBIS Pharmacopoeial Certificate of Suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturerB.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active					
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CAPOLEV TABLET 4MGCAPOLEV TABLET 					an active substance For a starting material/reagent/intermediate used in
CAPOLEV TABLET CAPOLEV TABLET DELORBIS PHARMACEU to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 4MG 8327/23T TICALS LTD B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active					substance For an excipient - European
4MG 4MG 8327/23T TICALS LTD approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active					to the relevant Ph. Eur. Monograph -
CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active			8327/23T		approved manufacturer
Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active					CHANGES - CEP/TSE/MONOGRAPHS
an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active					Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
the manufacturing process of the active					an active substance For a starting
					the manufacturing process of the active substance For an excipient - European
CAPOLEV CAPOLEV DELORBIS Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -	CAPOLEV	CAPOLEV		DELORBIS	Pharmacopoeial Certificate of Suitability
TABLETTABLETPHARMACEUUpdated certificate from an already16MG16MG8325/23TTICALS LTDapproved manufacturer	TABLET		8325/23T	PHARMACEU	Updated certificate from an already
B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS					B.III.1.a.2 B.III.1.a.2 - QUALITY
- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion					- Submission of a new or updated Ph.
of Ph. Eur. certificate of suitability: For an active substance For a starting					of Ph. Eur. certificate of suitability: For
material/reagent/intermediate used in the manufacturing process of the active					material/reagent/intermediate used in
substance For an excipient - European Pharmacopoeial Certificate of Suitability					substance For an excipient - European
CAPOLEV CAPOLEV TABLET TABLET					to the relevant Ph. Eur. Monograph -
8MG 8MG 8326/23T TICALS LTD approved manufacturer			8326/23T		approved manufacturer
C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -					PHARMACOVIGILANCE CHANGES -
HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)					MEDICINAL PRODUCTS - Change(s)
in the Summary of Product Characteristics, Labelling or Package					Characteristics, Labelling or Package
Leaflet of human medicinal products intended to implement the outcome of a					intended to implement the outcome of a
procedure concerning PSUR or PASS, or the outcome of the assessment done					
LEVOSYNT LEVOSYNT by the competent authority under Articles 45 or 46 of Regulation	LEVOSYNT	LEVOSYNT			Articles 45 or 46 of Regulation
TABLETTABLETCODAL1901/2006 - Implementation of wording100/10MG100/10MG8349/23TSYNTO LTDagreed by the competent authority			8349/23T		1901/2006 - Implementation of wording agreed by the competent authority
C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY					PHARMACOVIGILANCE CHANGES -
MEDICINAL PRODUCTS - Change(s) in the Summary of Product					MEDICINAL PRODUCTS - Change(s)
Characteristics, Labelling or Package Leaflet of human medicinal products					Characteristics, Labelling or Package
intended to implement the outcome of a					intended to implement the outcome of a
LEVOSYNTLEVOSYNTprocedure concerning PSUR or PASS, or the outcome of the assessment doneTABLETTABLETCODALor the outcome of the assessment done250/25MG250/25MG8350/23TSYNTO LTDby the competent authority under					or the outcome of the assessment done

				Articles 45 or 46 of Regulation
				1901/2006 - Implementation of wording
				agreed by the competent authority
				A.1 A.1 - ADMINISTRATIVE
LEVOSYNT	LEVOSYNT		0004	CHANGES - Change in the name
TABLET 250/25MG	TABLET 250/25MG	9252/22T	CODAL SYNTO LTD	and/or address of the marketing authorisation holder
250/25101G	250/251013	8252/23T	STNICLID	A.1 A.1 - ADMINISTRATIVE
LEVOSYNT	LEVOSYNT			CHANGES - Change in the name
TABLET	TABLET		CODAL	and/or address of the marketing
100/10MG	100/10MG	8251/23T	SYNTO LTD	authorisation holder
				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
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	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
		0007/201,0000/201		B.II.d.2.b B.II.d.2.b - QUALITY
COPAXON E SOLUTION FOR INJECTION IN PREFILLED SYRINGE	COPAXON E SOLUTION FOR INJECTION IN PREFILLED SYRINGE	6978/23T, 6979/23T,		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 or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to
40MG/ML	40MG/ML CURILEN	6980/23T, 6981/23T	TEVA GMBH UNI-PHARMA	an approved test procedure
CURITEN				
CURILEN CAPSULE,	CAPSULE,		KLEON	A.2.b A.2.b - ADMINISTRATIVE

10MG/100M G	10MG/100M G		PHARMACEU TICAL LABORATORI ES SA	name of the medicinal product - for Nationally Authorised Products
CURILEN CAPSULE, HARD 5MG/100M G	CURILEN CAPSULE, HARD 5MG/100M G	7189/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES SA	A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products
MANTOME D TABLET, FILM COATED 20MG	MANTOME D TABLET, FILM COATED 20MG	3047/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOME D TABLET, FILM COATED 5MG	MANTOME D TABLET, FILM COATED 5MG	3046/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOME D TABLET, FILM COATED 10MG	MANTOME D TABLET, FILM COATED 10MG	3048/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOME D TABLET, FILM COATED 15MG	MANTOME D TABLET, FILM COATED 15MG	3045/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
METHOTR EXATE TABLET, FILM COATED 2.5MG	METHOTR EXATE 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
ABIRATER ONE/SAND OZ TABLET, FILM COATED 500MG	ABIRATER ONE/SAND OZ TABLET, FILM COATED 500MG	6972/23T, 6973/23T, 6974/23T	SANDOZ PHARMACEU TICALS 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	AMLODIPIN ACCORD TABLET		ACCORD HEALTHCARE	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active 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

			active substance, intermediate or
			finished product, packaging site, manufacturer 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)
			A.7 A.7 - ADMINISTRATIVE CHANGES
			- Deletion of manufacturing sites for an active substance, intermediate or
			finished product, packaging site, manufacturer responsible for batch
AMLODIPIN AMLO			release, site where batch control takes
ACCORD ACCO TABLET TABLE		ACCORD HEALTHCARE	place, or supplier of a starting material, reagent or excipient (when mentioned in
5MG 5MG	8230/23T, 8231/23T		the dossier)* 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
AMLODIPIN AMLOI		ACCORD	finished product - Addition of a new specification parameter to the
TABLET TABLE 10MG 10MG		HEALTHCARE S.L.U	specification with its corresponding test method
	1092/231	3.L.0	B.II.e.2.b B.II.e.2.b - QUALITY
			CHANGES - FINISHED PRODUCT - Container closure system - Change in
			the specification parameters and/or
AMLODIPIN AMLOI	DIPIN		limits of the immediate packaging of the finished product - Addition of a new
ACCORD ACCOR TABLET TABLE		ACCORD HEALTHCARE	specification parameter to the specification with its corresponding test
5MG 5MG	7893/23T	S.L.U	method
			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
APIXABAN APIXA	BAN		of, or changes to, a summary of pharmacovigilance system for medicinal
FARMAPR FARM			products for human use* - Introduction
OJECTS OJECT TABLET, TABLE			of a summary of pharmacovigilance system, changes in QPPV (including
FILM FILM COATED COATE	ED	FARMAPROJE	contact details) and/or changes in the Pharmacovigilance System Master File
2.5MG 2.5MG	4415/23T, 4416/23T		(PSMF) location
APIXABAN APIXA FARMAPR FARM			A.2.b A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented)
OJECTS OJECT TABLET, TABLE			name of the medicinal product - for Nationally Authorised Products
FILM FILM			C.I.8.a C.I.8.a - SAFETY, EFFICACY,
COATED COATE 5MG 5MG	ED 4413/23T, 4414/23T	FARMAPROJE CTS, S.A.U	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location B.II.b.2.a B.II.b.2.a - QUALITY
GLIZOREM TABLET 80MG	GLIZOREM TABLET 80MG	8108/23T	REMEDICA LTD	CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place A.5.b A.5.b - ADMINISTRATIVE
PACLITAXE L HOSPIRA CONCENT RATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXE L HOSPIRA CONCENT RATE FOR SOLUTION FOR INFUSION 6MG/ML	8074/23T, 8075/23T, 8076/23T	PFIZER HELLAS AE	CHANGES - Change in the name and/or address of a manufacturer/importer of the 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
SOLPADEI NE COLD & FLU CAPSULE, HARD 500MG/100 MG/6.1MG	SOLPADEI NE COLD & FLU CAPSULE, HARD 500MG/100 MG/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 TRANSDER MAL GEL 16.2 MG/G	TESTOGEL TRANSDER MAL GEL 16.2 MG/G	7743/23T	LABORATOIR ES BESINS INTERNATION AL	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active 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	OCTAPHARM A (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	OCTAPHARM A (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/I NJECTION 1G	FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/I NJECTION 1G	6346/23T	OCTAPHARM A (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 SUSPENSI ON FOR INJECTION 15MCG/0.5 ML	FLUARIX TETRA SUSPENSI ON FOR INJECTION 15MCG/0.5 ML	7564/23T	GLAXOSMITH KLINE 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
MONTELU KAST KRKA TABLET, CHEWABL E 4MG	MONTELU KAST KRKA TABLET, CHEWABL E 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
MONTELU KAST KRKA TABLET, FILM COATED 10MG	MONTELU KAST 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
MONTELU KAST KRKA TABLET, CHEWABL E 5MG	MONTELU KAST KRKA TABLET, CHEWABL E 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
ATAZANAV IR REMEDICA CAPSULE, HARD 200MG	ATAZANAV IR 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
ATAZANAV IR REMEDICA	ATAZANAV IR 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

HARD HARD					
300MG 300MG C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH REMEDICA AF32UNLF, HARD CAPSULE, HARD C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH ATAZANAV IR REMEDICA C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH ATAZANAV IR REMEDICA C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH ATAZANAV IR REMEDICA C.I.2 a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH IOMG 100MG 8064/23T LTD Bill 1.2 a B ill 1.2 a C UALITY CHANGES - CEPTSE/MONOGRAPHS - Submission of a new or updated Ph. EVE VF EYE DROPS, SUSPENSI SUSPENSI NOVARTIS UN - 0.3% w/v W/v + 0.3% w/v 617723T UMITED Bill 1.2 a B ill 1.2 a C UALITY CHANGES - CEPTSE/MONOGRAPHS - Submission of a nexcipient - European Pharmacopoeial Certificate of Suitability or an active substance For a nexcipient - European Pharmacopoeial Certificate of Suitability contractificate of Suitability or an active substance For a nexcipient - European Pharmacopoeial Certificate of Suitability contractificate of suitability or con an active substance For a nexcipient - European Pharmacopoeial Certificate of Sui	CAPSULE,	CAPSULE,			
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GASTRO- RESISTAN T 20MGGASTRO- RESISTAN T 20MGGASTRO- RESISTAN T 20MGGASTRO- RESISTAN T 20MGto the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturerImage: Clipped					
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IRON/MLIRON/ML2537/23TFRANCEby the competent authority is required*SUGAMMASUGAMMA7290/23T, 7291/23T,B.I.z B.I.z - Quality change - ActiveDEXDEX7292/23T, 7293/23T,ANABIOSISsubstance - Other variation				VIFOR	
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DEX DEX 7292/23T, 7293/23T, ANABIOSIS substance - Other variation				1	
				ANABIOSIS	
	ANABIOSIS	ANABIOSIS	7294/23T, 7295/23T	PC.	B.I.a.2.e B.I.a.2.e - QUALITY

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SOLUTION	SOLUTION			CHANGES - ACTIVE SUBSTANCE -
FOR	FOR			Manufacture - Changes in the
INJECTION 100MG/ML	INJECTION 100MG/ML			manufacturing process of the active
TOOMG/INL	TOUIVIG/IVIL			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
				B.II.b.5.c B.II.b.5.c - QUALITY
REGAINE	REGAINE			CHANGES - FINISHED PRODUCT -
WOMEN'S	WOMEN'S		JOHNSON &	Manufacture - Change to in-process
FOAM	FOAM		JOHNSON	tests or limits applied during the
CUTANEO	CUTANEO		HELLAS	manufacture of the finished product -
US FOAM 5% W/W	US FOAM 5% W/W	7597/23T	CONSUMER AE	Deletion of a non-significant in-process
5% ٧٧/٧٧	5% /////	7597/231	AE	test B.II.b.4.a B.II.b.4.a - QUALITY
				CHANGES - FINISHED PRODUCT -
SYNTOCLA	SYNTOCLA			Manufacture - Change in the batch size
V TABLET,	V TABLET,			(including batch size ranges) of the
FILM	FILM		CODAL-	finished product - Up to 10-fold
COATED	COATED		SYNTO	compared to the originally approved
875/125MG	875/125MG	8172/23T	LIMITED	batch size
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
METHOTR	METHOTR			intended to implement the outcome of a
EXATE	EXATE			procedure concerning PSUR or PASS,
ACCORD	ACCORD			or the outcome of the assessment done
SOLUTION	SOLUTION			by the competent authority under
FOR	FOR		ACCORD	Articles 45 or 46 of Regulation
		2054/22T	HEALTHCARE	1901/2006 - Implementation of wording
25MG/ML	25MG/ML	2054/23T	S.L.U	agreed by the competent authority B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
				Changes - Finished PRODUCT - Container closure system - Change in
STERCOR	STERCOR			immediate packaging of the finished
E TABLET,	E TABLET,			product - Change in type of container or
FILM	FILM			addition of a new container - Solid,
COATED	COATED		MEDOCHEMIE	semi-solid and non-sterile liquid
1MG	1MG	4968/23T	LTD	pharmaceutical forms
				B.II.e.1.b.1 B.II.e.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
OTEDOOD	0750000			Container closure system - Change in
STERCOR	STERCOR			immediate packaging of the finished
E TABLET, FILM	E TABLET, FILM			product - Change in type of container or
COATED	COATED		MEDOCHEMIE	addition of a new container - Solid, semi-solid and non-sterile liquid
2MG	2MG	4967/23T	LTD	pharmaceutical forms
				B.II.b.3.a B.II.b.3.a - QUALITY
	LANSO			
LANSO GASTRO-	LANSO GASTRO-		IASIS	CHANGES - FINISHED PRODUCT -
LANSO		8054/23T	IASIS PHARMACEU	

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 B.II.b.3.z B.II.b.3.z - QUALITY
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.	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	SYRINGE 20MG(2000			product - Change in the holding time of an intermediate
IU)/0.2ML	IU)/0.2ML			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
CLEXANE	CLEXANE			size up to 10-fold for the pharmaceutical form medicinal gas B.I.e.5.c B.I.e.5.c - QUALITY
SOLUTION	SOLUTION			CHANGES - ACTIVE SUBSTANCE -
FOR INJECTION IN	INJECTION			Design Space and post-approval change management protocols - Implementation of changes foreseen in
PREFILLED	PREFILLED		SANOFI	an approved change management protocol - Implementation of a change
80MG(8000 IU)/0.8ML	80MG(8000 IU)/0.8ML	6233/23T	WINTHROP INDUSTRIE.	for a biological/immunological medicinal product
CLEXANE SOLUTION	CLEXANE	0200/201	INDOOTHIE.	B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE -
FOR	FOR			Design Space and post-approval change management protocols -
IN PREFILLED	IN PREFILLED			Implementation of changes foreseen in an approved change management
SYRINGE 40MG(4000	SYRINGE 40MG(4000		SANOFI WINTHROP	protocol - Implementation of a change for a biological/immunological medicinal
IU)/0.4ML CLEXANE	IU)/0.4ML CLEXANE	6235/23T	INDUSTRIE.	product B.I.e.5.c B.I.e.5.c - QUALITY
SOLUTION FOR	SOLUTION FOR			CHANGES - ACTIVE SUBSTANCE - Design Space and post-approval
INJECTION IN	INJECTION IN			change management protocols - Implementation of changes foreseen in
PREFILLED SYRINGE	PREFILLED SYRINGE		SANOFI	an approved change management protocol - Implementation of a change
20MG(2000 IU)/0.2ML	20MG(2000 IU)/0.2ML	6236/23T	WINTHROP INDUSTRIE.	for a biological/immunological medicinal product
CLEXANE SOLUTION	CLEXANE SOLUTION			B.I.e.5.c B.I.e.5.c - QUALITY CHANGES - ACTIVE SUBSTANCE -
FOR INJECTION IN	FOR INJECTION			Design Space and post-approval change management protocols -
PREFILLED	IN PREFILLED SYRINGE		SANOFI	Implementation of changes foreseen in an approved change management protocol - Implementation of a change
60MG(6000 IU)/0.6ML	60MG(6000 IU)/0.6ML	6234/23T	WINTHROP INDUSTRIE.	for a biological/immunological medicinal product
				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
CLEXANE SOLUTION	CLEXANE SOLUTION			form medicinal gas B.II.b.3.a B.II.b.3.a - QUALITY
FOR INJECTION	FOR INJECTION			CHANGES - FINISHED PRODUCT - Manufacture - Change in the
IN PREFILLED	IN PREFILLED		SANOFI	manufacturing process of the finished product, including an intermediate used
SYRINGE 20MG(2000 IU)/0.2ML	SYRINGE 20MG(2000 IU)/0.2ML	4927/23T, 4928/23T	SANOFI WINTHROP	in the manufacture of the finished product - Minor change in the manufacturing process
CLEXANE	CLEXANE	43211231,4320/231	INDUSTRIE.	manufacturing process B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT -
SOLUTION	SOLUTION			Manufacture - Change in the batch size (including batch size ranges) of the
INJECTION	INJECTION			finished product - Increase of the batch size up to 10-fold for the pharmaceutical
PREFILLED	PREFILLED SYRINGE		SANOFI	form medicinal gas B.II.b.3.a B.II.b.3.a - QUALITY
80MG(8000 IU)/0.8ML	80MG(8000 IU)/0.8ML	4921/23T, 4922/23T	WINTHROP INDUSTRIE.	CHANGES - FINISHED PRODUCT - Manufacture - Change in the

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				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
CLEXANE SOLUTION	CLEXANE SOLUTION			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
FOR INJECTION IN	FOR INJECTION IN			CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished
PREFILLED SYRINGE	PREFILLED SYRINGE		SANOFI WINTHROP	product, including an intermediate used in the manufacture of the finished
40MG(4000 IU)/0.4ML	40MG(4000 IU)/0.4ML	4925/23T, 4926/23T	INDUSTRIE.	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
CLEXANE	CLEXANE			finished product - Increase of the batch size up to 10-fold for the pharmaceutical
SOLUTION FOR	SOLUTION FOR			form medicinal gas B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT -
INJECTION IN PREFILLED	INJECTION IN PREFILLED			Manufacture - Change in the manufacturing process of the finished product, including an intermediate used
SYRINGE 60MG(6000 IU)/0.6ML	SYRINGE 60MG(6000 IU)/0.6ML	4923/23T, 4924/23T	SANOFI WINTHROP INDUSTRIE.	in the manufacture of the finished product - Minor change in the manufacturing process
			INDOGINE.	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
CLEXANE	CLEXANE			protocol - Implementation of a change for a biological/immunological medicinal
SOLUTION FOR INJECTION	SOLUTION FOR INJECTION			product B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE -
IN PREFILLED SYRINGE	IN PREFILLED SYRINGE		SANOFI	Manufacture - Changes in the manufacturing process of the active substance - Minor change in the
80MG(8000 IU)/0.8ML	80MG(8000 IU)/0.8ML	4556/23T, 4557/23T	WINTHROP INDUSTRIE.	manufacturing process of the active substance 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
CLEXANE SOLUTION	CLEXANE SOLUTION			protocol - Implementation of a change for a biological/immunological medicinal product
FOR INJECTION	FOR INJECTION			B.I.a.2.a B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE -
IN PREFILLED SYRINGE	IN PREFILLED SYRINGE		SANOFI	Manufacture - Changes in the manufacturing process of the active substance - Minor change in the
40MG(4000 IU)/0.4ML CLEXANE	40MG(4000 IU)/0.4ML	4560/23T, 4561/23T	WINTHROP INDUSTRIE.	manufacturing process of the active substance B.I.e.5.c B.I.e.5.c - QUALITY
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

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INJECTION	INJECTION			change management protocols -
IN	IN			Implementation of changes foreseen in
PREFILLED	PREFILLED			an approved change management
SYRINGE	SYRINGE			protocol - Implementation of a change
60MG(6000	60MG(6000			for a biological/immunological medicinal
IU)/0.6ML	IU)/0.6ML			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
				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
CLEXANE	CLEXANE			for a biological/immunological medicinal
SOLUTION	SOLUTION			product
FOR	FOR			B.I.a.2.a B.I.a.2.a - QUALITY
INJECTION	INJECTION			CHANGES - ACTIVE SUBSTANCE -
IN	IN			Manufacture - Changes in the
PREFILLED	PREFILLED			manufacturing process of the active
SYRINGE	SYRINGE		SANOFI	substance - Minor change in the
20MG(2000	20MG(2000		WINTHROP	manufacturing process of the active
IU)/0.2ML	IU)/0.2ML	4562/23T, 4563/23T	INDUSTRIE.	substance
10,0.2111		1002/201, 1000/201		B.II.d.2.a B.II.d.2.a - QUALITY
VISIOLATA	VISIOLATA			CHANGES - FINISHED PRODUCT -
NEYE	NEYE		BAUSCH +	Control of finished product - Change in
	DROPS,		LOMB	test procedure for the finished product -
DROPS,			IRELAND	
SOLUTION	SOLUTION	6210/22T		Minor changes to an approved test
50MCG/ML	50MCG/ML	6210/23T	LIMITED	procedure
ZOLEDRO	ZOLEDRO			
NIC ACID				B.II.d.1.a B.II.d.1.a - QUALITY
ALTAN	ALTAN			CHANGES - FINISHED PRODUCT -
SOLUTION	SOLUTION		AL TAN	Control of finished product - Change in
FOR	FOR		ALTAN	the specification parameters and/or
INFUSION	INFUSION	0540/007	PHARMACEU	limits of the finished product -
4MG/100ML	4MG/100ML	6546/23T	TICALS S.A.	Tightening of specification limits
				B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change to importer,
FOLIERO	FOUEDOW			batch release arrangements and quality
ESMERON	ESMERON			control testing of the finished product -
SOLUTION	SOLUTION			Replacement or addition of a
FOR	FOR			manufacturer responsible for
INJECTION	INJECTION			importation and/or batch release - Not
50MG/5ML	50MG/5ML	8016/23T	MSD AFVEE	including batch control/testing
MABRON	MABRON			
RETARD	RETARD			
TABLET,	TABLET,			
PROLONG	PROLONG			A.1 A.1 - ADMINISTRATIVE
ED-	ED-			CHANGES - Change in the name
RELEASE	RELEASE		MEDOCHEMIE	and/or address of the marketing
100MG	100MG	7813/23T	LTD	authorisation holder
MABRON	MABRON			
RETARD	RETARD			
TABLET,	TABLET,			
PROLONG	PROLONG			A.1 A.1 - ADMINISTRATIVE
ED-	ED-			CHANGES - Change in the name
RELEASE	RELEASE		MEDOCHEMIE	and/or address of the marketing
200MG	200MG	7811/23T	LTD	authorisation holder
MABRON	MABRON			
RETARD	RETARD			A.1 A.1 - ADMINISTRATIVE
TABLET,	TABLET,			CHANGES - Change in the name
PROLONG	PROLONG		MEDOCHEMIE	and/or address of the marketing
ED-	ED-	7812/23T	LTD	authorisation holder

RELEASE	RELEASE			
150MG	150MG			
MAINTELY TE SOLUTION FOR INFUSION 50MG/ML SEVOFLUR	MAINTELY TE SOLUTION FOR INFUSION 50MG/ML SEVOFLUR	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 B.II.e.1.a.2 B.II.e.1.a.2 - QUALITY
ANE- PIRAMAL INHALATIO N VAPOUR, LIQUID 100% V/V	ANE- PIRAMAL INHALATIO N VAPOUR, LIQUID 100% V/V	6362/23T	PIRAMAL CRITICAL CARE B.V.	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	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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

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COATED 140MG	COATED 140MG			substance or intermediate used in the
1401010	1401010			manufacturing process of the active substance - Up to 10-fold increase
				compared to the originally approved
				batch size
				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
SPECENIB	SPECENIB			substance or intermediate used in the
TABLET,	TABLET,			manufacturing process of the active
FILM	FILM			substance - Up to 10-fold increase
COATED	COATED	7000/007	REMEDICA	compared to the originally approved
20MG	20MG	7836/23T	LTD	batch size 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
SPECENIB	SPECENIB			substance or intermediate used in the
TABLET,	TABLET,			manufacturing process of the active
FILM COATED	FILM COATED		REMEDICA	substance - Up to 10-fold increase compared to the originally approved
80MG	80MG	7833/23T	LTD	batch size
				B.I.a.3.a B.I.a.3.a - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
				Manufacture - Change in batch size
SPECENIB	SPECENIB			(including batch size ranges) of active substance or intermediate used in the
TABLET,	TABLET,			manufacturing process of the active
FILM	FILM			substance - Up to 10-fold increase
COATED	COATED		REMEDICA	compared to the originally approved
70MG	70MG	7834/23T	LTD	batch size
CEFTRIX POWDER	CEFTRIX POWDER			
AND	AND			
SOLVENT	SOLVENT			
FOR	FOR			
SOLUTION FOR	SOLUTION FOR		CODAL-	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
INJECTION	INJECTION		SYNTO	and/or address of the marketing
1G/VIAL	1G/VIAL	8001/23T	LIMITED	authorisation holder
CEFTRIX	CEFTRIX			
POWDER	POWDER			
AND SOLVENT	AND SOLVENT			
FOR	FOR			
SOLUTION	SOLUTION			
FOR	FOR			A.1 A.1 - ADMINISTRATIVE
INJECTION	INJECTION		CODAL-	CHANGES - Change in the name
500MG/VIA L	500MG/VIA L	8002/23T	SYNTO LIMITED	and/or address of the marketing authorisation holder
<u> </u>				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 -
		6428/23T, 6429/23T,		Manufacture - Change to in-process
		6430/23T, 6431/23T,		tests or limits applied during the
TABLET, DISPERSIB	TABLET, DISPERSIB	6432/23T, 6433/23T, 6434/23T, 6435/23T,	PFIZER	manufacture of the finished product - Deletion of a non-significant in-process
LE 20MG	LE 20MG	6436/23T	HELLAS AE	test
				B.II.b.3.a B.II.b.3.a - QUALITY
				CHANGES - FINISHED PRODUCT -
FELDENE	FELDENE			Manufacture - Change in the
TABLET, DISPERSIB	TABLET, DISPERSIB		PFIZER	manufacturing process of the finished product, including an intermediate used
LE 20MG	LE 20MG	6417/23T	HELLAS AE	in the manufacture of the finished
		0111/201		

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				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	INNOHEP			
SOLUTION FOR INJECTION IN PREFILLED SYRINGE 4.500 ANTI- XA IU/0.45ML	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	INNOHEP	4003/201	7,0	
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 INNOHEP	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
SOLUTION FOR INJECTION IN PREFILLED SYRINGE 10.000 ANTI-XA IU/0.5ML	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
ESOMEPR AZOLE KRKA GASTRO- RESISTAN T CAPSULE, HARD 40MG	ESOMEPR AZOLE KRKA GASTRO- RESISTAN T 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
ESOMEPR AZOLE KRKA GASTRO- RESISTAN T CAPSULE, HARD 20MG	ESOMEPR AZOLE KRKA GASTRO- RESISTAN T 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

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ALMIRAL	ALMIRAL			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 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, over the toth release batch exerted
GEL 1% W/W	GEL 1% W/W	8280/23T, 8281/23T, 8282/23T	MEDOCHEMIE LTD	except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
TOPOTECA N ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 1MG/ML	TOPOTECA N ACCORD CONCENT RATE 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/I NJECTION 1G	FIBRYGA POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/I NJECTION 1G	7572/23T	OCTAPHARM A (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
MYCOPHE NOLIC ACID ACCORD TABLET, GASTRO- RESISTAN T 180MG	MYCOPHE NOLIC ACID ACCORD TABLET, GASTRO- RESISTAN T 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
MYCOPHE NOLIC ACID ACCORD TABLET, GASTRO- RESISTAN T 360MG	MYCOPHE NOLIC ACID ACCORD TABLET, GASTRO- RESISTAN T 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
FLUDARAB INE ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION AND INJECTION 25MG/ML	FLUDARAB INE ACCORD CONCENT RATE 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 -

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				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)*
				A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
FINASTERI	FINASTERI			and/or address of a
D	D			manufacturer/importer of the finished
			AUROBINDO	product (including batch release or quality control testing sites) - The
O TABLET, FILM	O TABLET, FILM		PHARMA	activities for which the
COATED	COATED		(MALTA)	manufacturer/importer is responsible do
5MG	5MG	2533/23T, 2534/23T	LIMITED	not include batch release
МҮСОРНЕ	МҮСОРНЕ			A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
NOLIC	NOLIC			and/or address of a
ACID	ACID			manufacturer/importer of the finished
ACCORD TABLET,	ACCORD TABLET,			product (including batch release or quality control testing sites) - The
GASTRO-	GASTRO-		ACCORD	activities for which the
RESISTAN	RESISTAN		HEALTHCARE	manufacturer/importer is responsible do
T 180MG	T 180MG	7225/23T	S.L.U	not include batch release
MYCOPHE	MYCOPHE			A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
NOLIC	NOLIC			and/or address of a
ACID	ACID			manufacturer/importer of the finished
ACCORD TABLET,	ACCORD TABLET,			product (including batch release or quality control testing sites) - The
GASTRO-	GASTRO-		ACCORD	activities for which the
RESISTAN	RESISTAN		HEALTHCARE	manufacturer/importer is responsible do
T 360MG	T 360MG	7224/23T	S.L.U	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 - 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
GAVISCON DOUBLE	GAVISCON DOUBLE		RECKITT	B.II.b.4.b B.II.b.4.b - QUALITY CHANGES - FINISHED PRODUCT -
ACTION	ACTION		BENCKISER	Manufacture - Change in the batch size
TABLET,	TABLET,	5620/23T, 5621/23T,	HELLAS	(including batch size ranges) of the
CHEWABL	CHEWABL	5622/23T, 5623/23T,	HEALTHCARE	finished product - Downscaling down to
E	E	5624/23T	SA	10-fold

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SPIRONOL ACTONE ACCORD TABLET, FILM COATED 100MG	SPIRONOL ACTONE 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 B.II.d.1.c B.II.d.1.c - QUALITY
SPIRONOL ACTONE ACCORD TABLET, FILM COATED 25MG	SPIRONOL ACTONE ACCORD TABLET, FILM COATED 25MG	7878/23T	ACCORD HEALTHCARE S.L.U	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
NICORETT E QUICKSPR AY BERRY OROMUCO SAL SPRAY, SOLUTION 1MG/SPRA Y	NICORETT E QUICKSPR AY BERRY OROMUCO SAL SPRAY, SOLUTION 1MG/SPRA Y	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)
NICORETT E QUICKSPR AY OROMUCO SAL SPRAY, SOLUTION 1MG/DOSE	NICORETT E QUICKSPR AY OROMUCO SAL 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)
LEVOXACI N TABLET, FILM COATED 250MG	LEVOXACI N TABLET, FILM COATED 250MG	9778/20T	SAPIENS PHARMACEU TICALS 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*
LEVOXACI N TABLET, FILM COATED 500MG	LEVOXACI N TABLET, FILM COATED 500MG	9777/20T	SAPIENS PHARMACEU TICALS 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 INTERNATION AL 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 SUSPENSI ON 2%	VERMOX ORAL SUSPENSI ON 2%	7495/23T	JANSSEN- CILAG INTERNATION AL 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

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				to the relevant Ph. Eur. Monograph - Updated certificate from an already
				approved manufacturer
LEVOXACI	LEVOXACI			C.I.11 b) Implementation of change(s)
Ν	Ν			which require to be further substantiated
SOLUTION	SOLUTION		0.00	by new additional data to be submitted
FOR	FOR INFUSION		SAPIENS	by the MAH where significant
INFUSION 5MG/ML	5MG/ML	9779/20T	PHARMACEU TICALS LTD	assessment by the competent authority is required*
3100/10L		3773/201		A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer
				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
ZYVOXID	ZYVOXID			dossier) where no Ph. Eur. Certificate of
SOLUTION FOR	SOLUTION FOR			Suitability is part of the approved dossier; or a manufacturer of a novel
INFUSION	INFUSION		PFIZER	excipient (where specified in the
2MG/ML	2MG/ML	4310/23T, 4311/23T	HELLAS AE	technical dossier)
				A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer responsible for batch release, site
				where batch control takes place, or
				supplier of a starting material, reagent
				or excipient (when mentioned in the
				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
ZYVOXID	ZYVOXID			dossier) where no Ph. Eur. Certificate of
TABLET,	TABLET,			Suitability is part of the approved
FILM	FILM			dossier; or a manufacturer of a novel
COATED	COATED	1000/00T 1000/00T	PFIZER	excipient (where specified in the
600MG	600MG	4308/23T, 4309/23T	HELLAS AE	technical dossier) 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
PALONAN	PALONAN			limits of the finished product - Deletion
SOLUTION	SOLUTION			of a non-significant specification
FOR	FOR			parameter (e.g. deletion of an obsolete
INJECTION 250MCG/5	INJECTION 250MCG/5		ANFARM	parameter such as odour and taste or identification test for a colouring or
Z501VICG/5	ML	5812/21T	HELLAS S.A.	flavouring material)
PALONAN	PALONAN			B.I.z B.I.z - QUALITY CHANGES -
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	INJECTION			
250MCG/5	250MCG/5			
ML BUFAR EASYHALE R POWDER FOR INHALATIO N 320/9MCG/I NHALATIO N	ML 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	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 C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
ROSUVAD OR TABLET, FILM COATED 40MG	ROSUVAD OR TABLET, FILM COATED 40MG	3398/23T	TAD PHARMA GMBH	HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.z C.I.z - SAFETY, EFFICACY,
ROSUVAD OR TABLET, FILM	ROSUVAD OR TABLET, FILM	3401/23T	TAD PHARMA GMBH	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product

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COATED	COATED			Characteristics, Labelling or Package
5MG	5MG			Leaflet intended to implement the
				outcome of a PRAC signal
				recommendation: implementation of
				wording agreed by the competent
				authority that require additional minor
				assessment, e.g. translations are not
				yet agreed upon C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of product
				Characteristics, Labelling or Package
				Leaflet intended to implement the
ROSUVAD	ROSUVAD			outcome of a PRAC signal
OR	OR			recommendation: implementation of
TABLET,	TABLET,			wording agreed by the competent
FILM	FILM			authority that require additional minor
COATED	COATED		TAD PHARMA	assessment, e.g. translations are not
20MG	20MG	3399/23T	GMBH	yet agreed upon
				C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of product Characteristics, Labelling or Package
				Leaflet intended to implement the
ROSUVAD	ROSUVAD			outcome of a PRAC signal
OR	OR			recommendation: implementation of
TABLET,	TABLET,			wording agreed by the competent
FILM	FILM			authority that require additional minor
COATED	COATED		TAD PHARMA	assessment, e.g. translations are not
10MG	10MG	3400/23T	GMBH	yet agreed upon
OCTANATE	OCTANATE			
LV	LV			
POWDER	POWDER			
AND	AND			
SOLVENT	SOLVENT			
FOR	FOR			B.II.d.2.a B.II.d.2.a - QUALITY
SOLUTION FOR	SOLUTION FOR			CHANGES - FINISHED PRODUCT - Control of finished product - Change in
INJECTION	INJECTION			test procedure for the finished product -
200IU/ML(1	200IU/ML(1		OCTAPHARM	Minor changes to an approved test
000IU/5ML)	000IU/5ML)	6913/23T	A (IP) SPRL	procedure
OCTANATE	OCTANATE			
LV	LV			
POWDER	POWDER			
AND	AND			
SOLVENT	SOLVENT			
FOR	FOR			B.II.d.2.a B.II.d.2.a - QUALITY
SOLUTION	SOLUTION			CHANGES - FINISHED PRODUCT -
FOR	FOR			Control of finished product - Change in
INJECTION	INJECTION			test procedure for the finished product -
100IU/ML(5	100IU/ML(5	6014/22T		Minor changes to an approved test
00IU/5ML)	00IU/5ML) OCTANATE	6914/23T	A (IP) SPRL	procedure
OCTANATE POWDER	POWDER			
AND	AND			
SOLVENT	SOLVENT			
FOR	FOR			B.II.d.2.a B.II.d.2.a - QUALITY
SOLUTION	SOLUTION			CHANGES - FINISHED PRODUCT -
FOR	FOR			Control of finished product - Change in
INJECTION	INJECTION			test procedure for the finished product -
250/500 (50	250/500 (50		OCTAPHARM	Minor changes to an approved test
200/000 (00				
IU/ml)	IU/ml)	6916/23T	A (IP) SPRL	procedure
		6916/23T	A (IP) SPRL	B.II.d.2.a B.II.d.2.a - QUALITY
IU/ml) OCTANATE POWDER	IU/ml) OCTANATE POWDER	6916/23T		B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT -
IU/ml) OCTANATE	IU/ml) OCTANATE	6916/23T 6915/23T	OCTAPHARM A (IP) SPRL	B.II.d.2.a B.II.d.2.a - QUALITY

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(1 000IU/5ML)	OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 200IU/ML(1 000IU/5ML)	6048/23T	OCTAPHARM A (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(5 00IU/5ML)	OCTANATE LV POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 100IU/ML(5 00IU/5ML)	6049/23T	OCTAPHARM A (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	OCTAPHARM A (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	OCTAPHARM A (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, PROLONG ED- RELEASE 75MG	VENLAXIN TABLET, PROLONG ED- RELEASE 75MG	8068/23T	IASIS PHARMACEU TICALS 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 -

				Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a
LAMOTRIX	LAMOTRIX			procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation
TABLET 100MG	TABLET 100MG	8019/23T	MEDOCHEMIE LTD	1901/2006 - Implementation of wording agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done
LAMOTRIX TABLET 25MG	LAMOTRIX TABLET 25MG	8021/23T	MEDOCHEMIE LTD	by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under
LAMOTRIX TABLET 50MG	LAMOTRIX TABLET 50MG	8020/23T	MEDOCHEMIE LTD	Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
MEDOFLO	MEDOFLO			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 -
XINE TABLET, FILM COATED	XINE TABLET, FILM COATED	9014/00T 9015/00T	MEDOCHEMIE	Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site
200MG FLIXOTIDE DISKUS POWDER FOR	200MG FLIXOTIDE DISKUS POWDER FOR	8014/23T, 8015/23T	LTD GLAXOSMITH KLINE	C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
INHALATIO N 250MCG	INHALATIO N 250MCG	7288/23T	(IRELAND) LIMITED	in the Summary of Product Characteristics, Labelling or Package

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				Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
FLIXOTIDE DISKUS POWDER FOR INHALATIO N 100MCG	FLIXOTIDE DISKUS POWDER FOR INHALATIO N 100MCG	7289/23T	GLAXOSMITH KLINE (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 A.7 A.7 - ADMINISTRATIVE
DUINUM TABLET 50MG	DUINUM TABLET 50MG	8029/23T	MEDOCHEMIE LTD	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
UTROGES TAN VAGINAL CAPSULE, SOFT 300MG	UTROGES TAN 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
UTROGES TAN VAGINAL CAPSULE, SOFT 300MG	UTROGES TAN 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	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 C.I.z C.I.z - SAFETY, EFFICACY,
PROPOFO L MCT/LCT/F RESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML	PROPOFO L MCT/LCT/F RESENIUS 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

PROPOFO	PROPOFO			C.I.z C.I.z - SAFETY, EFFICACY,
	L			PHARMACOVIGILANCE CHANGES -
MCT/LCT/F	MCT/LCT/F			
RESENIUS	RESENIUS			MEDICINAL PRODUCTS - Change(s)
EMULSION FOR	EMULSION FOR			in the Summary of product Characteristics, Labelling or Package
INJECTION	INJECTION			Leaflet intended to implement the
/ INFUSION	/ INFUSION			outcome of a PRAC signal
20MG/ML	20MG/ML			recommendation: implementation of
IN PRE-	IN PRE-		FRESENIUS	wording agreed by the competent
FILLED	FILLED		KABI HELLAS	authority that do not require any further
SYRINGE	SYRINGE	4196/23T	AE	assessment
				C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
	DRODOFO			
PROPOFO L	PROPOFO L			MEDICINAL PRODUCTS - Change(s) in the Summary of product
MCT/LCT/F	MCT/LCT/F			Characteristics, Labelling or Package
RESENIUS	RESENIUS			Leaflet intended to implement the
EMULSION	EMULSION			outcome of a PRAC signal
FOR	FOR			recommendation: implementation of
INJECTION	INJECTION		FRESENIUS	wording agreed by the competent
/ INFUSION	/ INFUSION	1100/00 7	KABI HELLAS	authority that do not require any further
20MG/ML	20MG/ML	4198/23T	AE	
PROPOFO	PROPOFO			C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
L MCT/LCT/F	L MCT/LCT/F			HUMAN AND VETERINARY
RESENIUS	RESENIUS			MEDICINAL PRODUCTS - Change(s)
EMULSION	EMULSION			in the Summary of product
FOR	FOR			Characteristics, Labelling or Package
INJECTION	INJECTION			Leaflet intended to implement the
/ INFUSION	/ INFUSION			outcome of a PRAC signal
10MG/ML	10MG/ML			recommendation: implementation of
IN PRE-	IN PRE-		FRESENIUS	wording agreed by the competent
FILLED	FILLED	4407/22T	KABI HELLAS	authority that do not require any further
SYRINGE	SYRINGE	4197/23T	AE	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
				C.I.2.b C.I.2.b - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
DRODOFO	DRODOFO			in the Summary of Product Characteristics, Labelling or Package
PROPOFO L	PROPOFO L			Leaflet of a generic/hybrid/biosimilar
MCT/LCT/F	L MCT/LCT/F			medicinal products following
RESENIUS	RESENIUS			assessment of the same change for the
EMULSION	EMULSION			reference product - Implementation of
FOR	FOR			change(s) which require to be further
INJECTION	INJECTION		FRESENIUS	substantiated by new additional data to
/ INFUSION	/ INFUSION	0444/04T	KABI HELLAS	be submitted by the MAH (e.g.
10MG/ML	10MG/ML	6111/21T	AE	
PROPOFO	PROPOFO			C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
			1	
L MCT/LCT/F	L MCT/LCT/F			HUMAN AND VETERINARY
MCT/LCT/F RESENIUS	L MCT/LCT/F RESENIUS			HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
MCT/LCT/F	MCT/LCT/F		FRESENIUS	HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product
MCT/LCT/F RESENIUS	MCT/LCT/F RESENIUS	6110/21T	FRESENIUS KABI HELLAS AE	MEDICINAL PRODUCTS - Change(s)

/ INFUSION	/ INFUSION			medicinal products following
20MG/ML	20MG/ML			assessment of the same change for the
				reference product - Implementation of
				change(s) for which no new additional
				data is required to be submitted by the
				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.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar
				medicinal products following
				assessment of the 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 -
PROPOFO	PROPOFO			HUMAN AND VETERINARY
L	L			MEDICINAL PRODUCTS - Change(s)
MCT/LCT/F	MCT/LCT/F			in the Summary of Product
RESENIUS	RESENIUS			Characteristics, Labelling or Package
EMULSION	EMULSION			Leaflet of a generic/hybrid/biosimilar
FOR	FOR			medicinal products following
INJECTION	INJECTION			assessment of the same change for the
/ INFUSION	/ INFUSION			reference product - Implementation of
20MG/ML	20MG/ML			change(s) which require to be further
IN PRE-	IN PRE-		FRESENIUS	substantiated by new additional data to
FILLED	FILLED		KABI HELLAS	be submitted by the MAH (e.g.
SYRINGE	SYRINGE	6108/21T	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
PROPOFO	PROPOFO			data is required to be submitted by the
L	L			MAH
MCT/LCT/F	MCT/LCT/F			C.I.2.b C.I.2.b - SAFETY, EFFICACY,
RESENIUS	RESENIUS			PHARMACOVIGILANCE CHANGES -
EMULSION	EMULSION			
FOR	FOR			MEDICINAL PRODUCTS - Change(s)
INJECTION / INFUSION	INJECTION / INFUSION			in the Summary of Product Characteristics, Labelling or Package
10MG/ML	10MG/ML			Leaflet of a generic/hybrid/biosimilar
IN PRE-	IN PRE-		FRESENIUS	medicinal products following
FILLED	FILLED		KABI HELLAS	assessment of the same change for the
SYRINGE	SYRINGE	6109/21T	AE	reference product - Implementation of
			•	

Subsimilated by new additional data to be submitted by the MAH (e.g., comparability) ENTEVIRE CLZ L2 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation M TABLET, IMM TABLET, FILM TTO CLZ CLZ - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation M TABLET, IMA TABLET, COATED TTO 2000 CLZ CLZ - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMANCOVIGILANCE CHANGES - HUMANCO					change(s) which require to be further
ENTEVIRE ENTEVIRE C1.2.C1.2: SAFETY, EFFICACY, PHARMACOVIGILANCE CHANCES, HUMAN AND VETERINARY PARMACOVIGILANCE CHANCES, HUMAN AND VETERINARY variation ENTEVIRE REMEDICA PHARMACOVIGILANCE CHANCES, HUMAN AND VETERINARY variation ENTEVIRE C1.2.C1.2: SAFETY, EFFICACY, PHARMACOVIGILANCE CHANCES, HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation COATED COATED CALE C1.2: SAFETY, EFFICACY, PHARMACOVIGILANCE CHANCES, HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation COATED COATED CALE C1.2: SAFETY, EFFICACY, PHARMACOVIGILANCE CHANCES, HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation COATED COATED CALE HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation COATED COATED CALE HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation COATED COATED CALE HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation COATED COATED AT A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing variation intermediate of Inished product, packaging site, manufacturer responsible for batch release, site whore batch control takes place, or variation (when mentioned in the dasier)'' INF + TAZOBACT INF + TAZOBACT AT A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing variation activation of manufacturing product (neutring material, reagent or accaline in the activation of manufacturing product in thel					substantiated by new additional data to be submitted by the MAH (e.g.
FILM FILM FILM HUMAN AND VETERINARY COATED CANTED REMEDICA LTD variation ENTEVIRE ENTEVIRE CL2 CL2 - SAFETY, EFFICACY, PHARAACOVIGILANCE CHANGES - HUMAN AND VETERINARY COATED O.SMG 7940/23T LTD CL2 CL2 - SAFETY, EFFICACY, PHARAACOVIGILANCE CHANGES - HUMAN AND VETERINARY COATED O.SMG 7940/23T LTD Variation COATED O.SMG 7940/23T LTD Variation PIPERACIL IN+ TAZOBACT AT A.7 - ADMINISTRATIVE CS ICS FOR FOR FOR FOR FOR FOR Intermediate or finished product, packaging site, manufacturing sites for an active substance, intermediate or finished product, qackaging site, manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturing sites for an active substance, intermediate or finished pr	ENTEVIRE	ENTEVIRE			
COATED COATED 7393/23T LTD MEDICIA MEDICINAL PRODUCTS - Other ENTEVIRE ENTEVIRE INTABLET, LTD C.1z - SAFETY, EFICACY, FILM FILM FILM C.1z - SAFETY, EFICACY, HUMAN AND VETERINARY COATED COATED 7840/23T LTD Variation OSMG 0.5MG 7940/23T LTD Variation PIPERACIL INTACOBACT A.7 A.7 - ADMINISTRATIVE CAARDOUCTS - Other CS ICS CHANCES - Deletion of manufacturing sites for an active substance, individe product, packaging site, manufacturer POWDER FOR FOR FOR SoluTION SOLUTION NELSON MYLAN Subplier of a staring material, reagent or exciptent (when mentioned in the date, site, or an active substance, for exciptent (when mentioned in the date) INPUSION INPUSION MYLAN Sites for an active substance, for an active sub					
1MG 1MG 7939/23T LTD variation ENTEVIRE C.12 C.12 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMA NAD VETERINARY COLVERINARY COATED COATED COATED PHARMACOVIGILANCE CHANGES - HUMAN ADV VETERINARY COATED COSME 7940/23T LTD variation PIPERACIL PIPERACIL IN AT A.7 - ADMINISTRATIVE CSS ICS POWDER sites for an active substance, intermediate or finished product, packaging site, manufacturing FOR FOR FOR manufacturing FOR FOR responsible for batch release, site where batch contont takes place, or supplier of a starting material, reagent or excipient (when mentioned in the data or finished product, packaging site, manufacturer FOR FOR TA208ACT A.7 A.7 - ADMINISTRATIVE ILIN + LIN + LI					
ENTEVIRE ENTEVIRE C.1z C.1z - SAFETY, EPTICACY, MTABLET, FILM			7939/23T	-	
FILM COATED FILM COATED FILM COATED HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation 0.5MG 7940/23T LTD HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation LIN + LIN + LIN + LIN + LIN + LIN CS LIN + LIN + LIN + LIN + CARBOPLA LIN + LIN + LIN + CARBOPLA AT A 7 - A DMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent of astarting material, reagent of astarting material, reagent of astarting material, reagent of exception of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent of astarting material, reagent of exception (when mentioned in the LIN + LIN + TAZOBACT LIN + TAZOBACT PIPERACIL LIN + TAZOBACT INFUSION INFUSION INFUSION FOR FOR FOR FOR FOR FOR FOR FOR FOR FOR	ENTEVIRE	ENTEVIRE			C.I.z C.I.z - SAFETY, EFFICACY,
COATED COATED REMEDICA MEDICINAL PRODUCTS - Other 05MG 0.5MG 7940/23T LTD variation PIPERACIL PIPERACIL LIN + LTD variation LIN + TAZOBACT TAZOBACT ANGENER AT A 7 - ADMINISTRATIVE CAS ICS ICS ICS POWDER POWDER POR FOR FOR FOR FOR FOR POR POR FOR FOR FOR FOR regensible for black herebase. site where black hourd lakes place. or INJECTION INJECTION MYLAN suppler of a starting metrial. reagent of excipient (when mentioned in the IAGOBER CHANGES - Deletion of manufacturing sites for an active substance. or INJECTION INJECTION MYLAN responsible for black hourd product. intermediate or finished product. INJECTION INJECTION INJECTION MYLAN responsible for black hourd. intermediate or finished product. INJECTION INJECTION INJECTION INFUSION M					
0.5MG 0.5MG 7940/23T LTD variation PIPERACL LIN +					_
LIN++ LIN++ TA20BACT TA20BACT TA20BACT TA20BACT TA20BACT TA20BACT POWDER FOR FOR FOR NUECTION			7940/23T	-	
TAZOBACT TAZOBACT AM/GENER CA NOWER CA FOR FOR FOR FOR FOR FOR NIJECTION Intermediate of finished product, packaging site, manufacturer NIFUSION NIFUSION (420.05G)V (430.05G)V (430.05G)V (430.05G)V (420.05G)V (440.05G)V (420.05G)V (450.05G)V (420.05G)V (460.05G)V (420.05G)V (460.05G)V (420.05G)V (460.05G)V (420.05G)V (460.05G)V (420.05G)V (460.05G)V (470.05G)V (460.05G)V (470.05G)V (460.05G)V (470.05G)V (460.05G)V<					
AM/GENER (CS AX 7.4.7 - ADMINISTRATIVE ICS CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* INJECTION INT INJECTION INT INT INT INT INT INT INT INT INT IN					
ICS ICS POWDER POWDER FOR FOR FOR FOR FOR FOR FOR FOR FOR FOR FOR INJECTION INJECTION Intermediate of finished product, packaging site, manufacturer INFUSION INFUSION MYLAN IAL 1AL 7369/23T ILIN + LIM + IMITED CARDACT TAZOBACT ATA A7 - ADMINISTRATIVE CHANGES - Deletion of manufacturer responsible for batch release, site MWEENER ATA A7 - ADMINISTRATIVE CHANGES - Deletion of manufacturer responsible for batch release, site MORDER FOR sites for an active substance, intermediate or finished product, packaging site, manufacturer FOR FOR responsible for batch release, site INFUSION INFUSION MYLAN INFUSION INFLEXION where batch control takes place, or SULITION SolutiTION responsible for batch release, site VIAL 7370/23T IMITED A5 a A 5 a - DMINISTRATIVE CARBOPLA TINHOSPI manufacturer					A.7 A.7 - ADMINISTRATIVE
FOR FOR FOR SOLUTION SOLUTION FOR intermediate or finished product, FOR INJECTION INJECTION myrel bach control takes place, or INJECTION INJECTION MYLAN supplier of a starting material, reagent (46/0.5G)/V (46/0.5G)/V RELAND or excipient (when mentioned in the LIN + LIN + LIMTED desire()* CARDACT TAZOBACT TAZOBACT A.7 A.7 - ADMINISTRATIVE CHINES ICS ICS ICS ICS POWDER FOR FOR intermediate or finished product, intermediate product, intermediate product, int					
SOLUTION FOR SOLUTION FOR packaging site, manufacturer FOR INJECTION INJEUSTION MYLAN supplier of a starting material, reagent IAL IAL 7369/23T LIMITED or excipient (when mentioned in the dossier)* IAL IAL 7369/23T LIMITED dessier)* PIPERACIL INFUSION A.7 A.7 - ADMINISTRATIVE LIN + LIN + TAZOBACT A.7 A.7 - ADMINISTRATIVE CS ICS CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer FOR FOR INJECTION MYLAN SOLUTION Supplier of a starting material, reagent (2G/0.25G)/ intermediate or finished product, prostal for batch release, site VIAL T370/23T IIMITED A.5.a - ADMINISTRATIVE CHANCES - Change in the name and/or address of a manufacturer/importer of the finished product (finduding batch release or quality control testing sites) - The activities for which the and/or address of a manufacturer/importer is responsible include batch release or quality control testing sites) - The activities for which the and/or address of amufacturer responsible for importation and/or batch release - Not including batch control testing, table, 2.1 - QUALITY CHANCES - FINISHED PRODUCT - Manufacture responsible for importation and/or batch					
FOR INJECTION (INFUSION) FOR (INJECTION) Feature for the field of the finished product (add).05G)/V Feature for the finished product (add).05G)/V IAL 7369/23T LIMITED dossier)* PIPERACIL LIN + TAZOBACT PIPERACIL LIN + LIN + TAZOBACT LIMITED dossier)* CARBOPLA AM/GENER AM/GENER A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or (INFUSION) VIAL 7370/23T MYLAN UIMTED A.7 A.7 - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release, site where batch control takes place, or (INFUSION) VIAL 7370/23T LIMITED A.5 a.4 S.6 - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the ac	-	-			
INJECTION INJECTION Where back control takes place, or (1NFUSION) (4G/0.5G)/V (4G/0.5G)/V IRELAND or excipient (when mentioned in the (4G/0.5G)/V (4G/0.5G)/V IAL 7369/23T LIMITED dossier)* PIPERACIL IN+ ILN+ ACT A.7 - ADMINISTRATIVE dossier)* CS ICS CHANGENER A.7 A.7 - ADMINISTRATIVE CS ICS CHANGENER intermediate or finished product, packaging site, manufacturer FOR FOR intermediate or finished product, packaging site, manufacturer responsible for bach release, or FOR FOR MYLAN supplier of a starting material, reagent C4G/0.25G)/ (2G/0.25G)/ (2G/0.25G)/ gastering material, reagent CARBOPLA TINHOSPI MYLAN supplier of a starting material, reagent CARBOPLA TINHOSPI MYLAN supplier of a starting material, reagent CG/0.25G)/ (2G/0.25G)/ CBANGEN MYLAN supplier of a starting material, reagent SOLUTION NOPRILAM T370/23T ILMITED A.5.a - ADMI					
(46/0.5G)/V (46/0.5G)/V IAL 7369/23T PIPERACIL PIPERACIL LIN + LIN + TAZOBACT A.7 A.7 - ADMINISTRATIVE CS ICS POWDER POWDER FOR FOR FOR FOR FOR FOR FOR FOR FOR FOR INJECTION INJECTION (26/0.25G)/ (26/0.25G)/ VIAL 7370/23T LIMITED dossier)* CARBOPLA CARBOPLA TIN/HOSPI RA RA RA RA RA RA RA RA RA CARBOPLA CARBOPLA TIN/HOSPI RA RA RA RA RA RA RA RA RA INFUSION INFUSION INFUSION INFUSION INFUSION POWDER FOR FOR FOR FOR					where batch control takes place, or
IAL 7369/23T LIMITED dossier)* PIPERACIL PIPERACIL PIPERACIL PIPERACIL LIN + LIN + LIN + A.7 A.7 - ADMINISTRATIVE CADDACT TAZOBACT A.7 A.7 - ADMINISTRATIVE CIN - CHANGES - Deletion of manufacturing sites for an active substance. intermediate or finished product, packaging site, manufacturer FOR FOR FOR FOR FOR FOR INFUSION INFUSION MYLAN (26/0.25G)/ (26/0.25G)/ (26/0.25G)/ VIAL 7370/23T IIMITED dossier)* CARBOPLA CARBOPLA A.5 a A.5 a - ADMINISTRATIVE CARBOPLA CARBOPLA TIN/HOSPI RA RA SOLUTION FOR FOR PFIZER INFUSION INFUSION PFIZER INFUSION INFUSION PFIZER INFUSION INFUSION PPIZER INFUSION TIN/HOSPI RA SOLUTION FOR FOR FOR					
PIPERACIL LIN + LIN + CARBORER FOR FOR FOR FOR INJECTION /INFUSION INJECTION /INFUSION /INFUSION (2G/0.25G)/ VIAL A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for a active substance, intermediate or finished product, packaging site, manufacturer 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 RA RA RA RA RA RA RA RA RA RA RA RA			7369/23T		
TAZOBACT TAZOBACT AM/GENER AM/GENER ICS ICS POWDER FOR FOR FOR FOR FOR SOLUTION SOLUTION YAL YAL YAL YAL <t< td=""><td>PIPERACIL</td><td>PIPERACIL</td><td></td><td></td><td></td></t<>	PIPERACIL	PIPERACIL			
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TOBI SOLUTION FOR INHALATIO N 300MG/5ML	TOBI SOLUTION FOR INHALATIO N 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
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PROLONG ED- RELEASE 5MG	PROLONG ED- 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, PROLONG ED- RELEASE 10MG	PLENDIL TABLET, PROLONG ED- RELEASE 10MG	7204/23T	ASTRAZENEC A 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, PROLONG ED- RELEASE 10MG	PLENDIL TABLET, PROLONG ED- RELEASE 10MG	7204/23T	ASTRAZENEC A 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, PROLONG ED- RELEASE 2.5MG	PLENDIL TABLET, PROLONG ED- RELEASE 2.5MG	7206/23T	ASTRAZENEC A 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, PROLONG ED- RELEASE 2.5MG	PLENDIL TABLET, PROLONG ED- RELEASE 2.5MG	7206/23T	ASTRAZENEC A 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, PROLONG ED- RELEASE 5MG	PLENDIL TABLET, PROLONG ED- RELEASE 5MG	4918/23T	ASTRAZENEC A 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, PROLONG ED- RELEASE 10MG	PLENDIL TABLET, PROLONG ED- RELEASE 10MG	4920/23T	ASTRAZENEC A 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, PROLONG ED- RELEASE 2.5MG	PLENDIL TABLET, PROLONG ED- RELEASE 2.5MG	4919/23T	ASTRAZENEC A 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
COROTRO PE TABLET 5MG	COROTRO PE TABLET 5MG	7912/23T, 7913/23T, 7914/23T, 7915/23T	REMEDICA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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 A.7 A.7 - ADMINISTRATIVE
ZITAMIN SOLUTION FOR INJECTION 2MG/ML	ZITAMIN SOLUTION FOR INJECTION 2MG/ML	5269/23T	NORIDEM ENTERPRISE S LTD	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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 ENTERPRISE S 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 ENTERPRISE S 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 ENTERPRISE S 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 ENTERPRISE S 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)*
SUGAMMA DEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	SUGAMMA DEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	8201/23T	SAPIENS PHARMACEU TICALS 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)
DARUNAVI R ACCORD TABLET, FILM COATED 600MG DARUNAVI	DARUNAVI R ACCORD TABLET, FILM COATED 600MG DARUNAVI	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 C.I.2.a C.I.2.a - SAFETY, EFFICACY,
R ACCORD TABLET, FILM COATED 800MG	R ACCORD TABLET, FILM COATED 800MG	4600/22T	ACCORD HEALTHCARE S.L.U	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package

				Leaflet of a generic/hybrid/biosimilar medicinal products following
				assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the
LOCERYL MEDICATE D NAIL LACQUER 5% (W/V)	LOCERYL MEDICATE D NAIL LACQUER 5% (W/V)	8271/22T, 8272/22T, 4287/23T	GALDERMA INTERNATION AL,FRANCE	MAH 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
SITAGLIPTI N/MYLAN TABLET, FILM COATED 50MG	SITAGLIPTI N/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
SITAGLIPTI N/MYLAN TABLET, FILM COATED 25MG	SITAGLIPTI N/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
SITAGLIPTI N/MYLAN TABLET, FILM COATED 100MG	SITAGLIPTI N/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
SITAGLIPTI N/MYLAN TABLET, FILM COATED 50MG	SITAGLIPTI N/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
HYDROCO RTISONE ACTIVASE	HYDROCO RTISONE ACTIVASE	8306/21T	ACTIVASE PHARMACEU TICALS LTD	C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

TABLET	TABLET			MEDICINAL PRODUCTS - Change(s)
10MG	10MG			in the Summary of Product
				Characteristics, Labelling 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.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
HYDROCO	HYDROCO			reference product - Implementation of
RTISONE	RTISONE			change(s) which require to be further
ACTIVASE	ACTIVASE		ACTIVASE	substantiated by new additional data to
TABLET	TABLET		PHARMACEU	be submitted by the MAH (e.g.
20MG	20MG	8307/21T	TICALS LTD	comparability)
				B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
HYDROCO	HYDROCO			Stability - Change in the shelf-life or
RTISONE	RTISONE			storage conditions of the finished
ACTIVASE	ACTIVASE		ACTIVASE	product - Extension of the shelf life of
TABLET	TABLET		PHARMACEU	the finished product - As packaged for
10MG	10MG	5558/22T	TICALS LTD	sale (supported by real time data)
101010	101010	3330/221	TICALS LTD	B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
HYDROCO	HYDROCO			Stability - Change in the shelf-life or
RTISONE	RTISONE			storage conditions of the finished
ACTIVASE	ACTIVASE		ACTIVASE	product - Extension of the shelf life of
TABLET	TABLET		PHARMACEU	the finished product - As packaged for
20MG	20MG	5557/22T	TICALS LTD	sale (supported by real time data)
SEROQUE	SEROQUE			
LXR	LXR			
TABLET,	TABLET,			
				A.1 A.1 - ADMINISTRATIVE
PROLONG ED-	PROLONG ED-			
				CHANGES - Change in the name
RELEASE	RELEASE	0700/007	ASTRAZENEC	and/or address of the marketing
300MG	300MG	3703/23T	A AB	authorisation holder
SEROQUE	SEROQUE			
L XR	L XR			
TABLET,	TABLET,			
PROLONG	PROLONG			A.1 A.1 - ADMINISTRATIVE
ED-	ED-			CHANGES - Change in the name
RELEASE	RELEASE		ASTRAZENEC	and/or address of the marketing
400MG	400MG	3704/23T	A AB	authorisation holder
TABLET,	TABLET,			
PROLONG	PROLONG			A.1 A.1 - ADMINISTRATIVE
ED-	ED-			CHANGES - Change in the name
RELEASE	RELEASE		ASTRAZENEC	and/or address of the marketing
5MG	5MG	3891/23T	A AB	authorisation holder
SEROQUE	SEROQUE			
L TABLET,	L TABLET,			A.1 A.1 - ADMINISTRATIVE
FILM	FILM			CHANGES - Change in the name
COATED	COATED		ASTRAZENEC	and/or address of the marketing
100MG	100MG	3699/23T	A AB	authorisation holder
		3033/231		
SEROQUE	SEROQUE			
L TABLET,	L TABLET,			A.1 A.1 - ADMINISTRATIVE
FILM	FILM			CHANGES - Change in the name
COATED	COATED		ASTRAZENEC	and/or address of the marketing
200MG	200MG	3700/23T	A AB	authorisation holder
	•	•	•	

SERCOUE SERCOUE LTABLET, FILM COATED COATED CATE CATE CATE CATE CATE CATE CATE CATE		SEROQUE			
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SED INHALATIO	SED INHALATIO			and/or address of the marketing authorisation holder
N,	N,			
SUSPENSI	SUSPENSI			
ON 80MCG/2.2	ON 80MCG/2.2			
5MCG/ACT	5MCG/ACT			
UATION	UATION			
PLENDIL TABLET,	PLENDIL TABLET,			
PROLONG	PROLONG			A.1 A.1 - ADMINISTRATIVE
ED-	ED-			CHANGES - Change in the name
RELEASE 10MG	RELEASE 10MG	3892/23T	ASTRAZENEC A AB	and/or address of the marketing authorisation holder
PLENDIL	PLENDIL	3032/231		
TABLET,	TABLET,			
PROLONG ED-	PROLONG ED-			A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
RELEASE	RELEASE		ASTRAZENEC	and/or address of the marketing
2.5MG	2.5MG	3890/23T	A AB	authorisation holder
				C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
DARUNAVI	DARUNAVI			medicinal products following
R ACCORD	R ACCORD			assessment of the same change for the
TABLET, FILM	TABLET, FILM		ACCORD	reference product - Implementation of change(s) for which no new additional
COATED	COATED		HEALTHCARE	data is required to be submitted by the
600MG	600MG	1630/23T	S.L.U	MAH
				C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar
DARUNAVI	DARUNAVI			medicinal products following
R ACCORD TABLET,	R ACCORD TABLET,			assessment of the same change for the reference product - Implementation of
FILM	FILM		ACCORD	change(s) for which no new additional
COATED	COATED		HEALTHCARE	data is required to be submitted by the
800MG	800MG	1629/23T	S.L.U	
				B.I.b.1.b B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE -
				Control of active substance - Change in
				the specification parameters and/or
				limits of an active substance, starting material / intermediate / reagent used in
ROCURONI	ROCURONI			the manufacturing process of the active
				substance - Tightening of specification
B.BRAUN SOLUTION	B.BRAUN SOLUTION			limits B.II.d.1.a B.II.d.1.a - QUALITY
FOR	FOR			CHANGES - FINISHED PRODUCT -
				Control of finished product - Change in
OR INFUSION	OR INFUSION	2802/23T, 2803/23T,	B. BRAUN MELSUNGEN	the specification parameters and/or limits of the finished product -
10MG/ML	10MG/ML	2804/23T	AG	Tightening of specification limits
			EGIS	C.I.z C.I.z - SAFETY, EFFICACY,
			PHARMACEU TICALS	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
			PRIVATE	MEDICINAL PRODUCTS - Change(s)
LIPOCOMB			LIMITED	in the Summary of product
CAPSULE, HARD	CAPSULE, HARD		COMPANY (EGIS	Characteristics, Labelling or Package Leaflet intended to implement the
10MG/10M	10MG/10M		GYÓGYSZER	outcome of a PRAC signal
G	G	2387/23T	GYÁR ZRT)	recommendation: implementation of

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				wording agreed by the competent authority that do not require any further assessment
LIPOCOMB CAPSULE, HARD 20MG/10M G	LIPOCOMB CAPSULE, HARD 20MG/10M G	2386/23T	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
LONATA EYE DROPS, SOLUTION (50MCG/5M G)/ML	LONATA EYE DROPS, SOLUTION (50MCG/5M G)/ML	4991/23T	PHARMATHE N 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
EMTRICITA BINE/TENO FOVIR DISOPROX IL ACCORDP HARMA TABLET, FILM COATED 200MG/245 MG	EMTRICITA BINE/TENO FOVIR DISOPROX IL ACCORDP HARMA TABLET, FILM COATED 200MG/245 MG	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
DIENOGES T BESINS TABLET 2MG	DIENOGES T BESINS TABLET 2MG	6002/23T	LABORATOIR ES BESINS INTERNATION AL	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
HYDROCO RTISONE RENATA TABLET 20MG	HYDROCO RTISONE RENATA TABLET 20MG	6896/23T, 6897/23T	RENATA PHARMACEU TICALS (IRELAND) LIMIED	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)*
HYDROCO RTISONE RENATA TABLET 10MG	HYDROCO RTISONE RENATA TABLET 10MG	6898/23T, 6899/23T	RENATA PHARMACEU TICALS (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

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EMTRICITA	EMTRICITA			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)*
BINE/TENO FOVIR DISOPROX IL ACCORDP HARMA TABLET, FILM COATED 200MG/245 MG	BINE/TENO FOVIR DISOPROX IL ACCORDP HARMA TABLET, FILM COATED 200MG/245 MG	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 CUTANEO US SOLUTION 5%	ANDROXIL CUTANEO US SOLUTION 5%	2577/22T, 2578/22T, 2579/22T, 2580/22T, 2581/22T	LABORATOIR ES 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 manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other

ANDROXIL CUTANEO US SOLUTION	ANDROXIL CUTANEO US SOLUTION	2582/22T, 2583/22T, 2584/22T, 2585/22T,	LABORATOIR ES BAILLEUL	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 site for part or all of the manufacturing site for part or all of the manufacture - Replacement or addition of a manufacturing site for part or all of the manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing site for part or all of the manufacturing site for part or all of
2%	2%	2586/22T	S.A	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)*
ALLOPURI NOL ACCORD TABLET 100MG	ALLOPURI NOL 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 C.I.11.z C.I.11.z - SAFETY,
ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L DEXMEDE TOMIDINE/ KABI	ALBIOMIN 20% SOLUTION FOR INFUSION 200G/L DEXMEDE TOMIDINE/ KABI	5652/23T	BIOTEST PHARMA GMBH FRESENIUS KABI HELLAS	C.I. TI.Z C.I. TI.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) A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a
CONCENT	CONCENT	5664/23T	A.E.	manufacturer/importer of the finished

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RATE FOR SOLUTION FOR	RATE FOR SOLUTION FOR			product (including batch release or quality control testing sites) - The activities for which the
INFUSION 100MCG/M L	INFUSION 100MCG/M L			manufacturer/importer is responsible do not include batch release
ZATEVEN TABLET 10MG/80M G	ZATEVEN TABLET 10MG/80M G	5049/23T	WIN MEDICA PHARMACEU TICAL 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/20M G	ZATEVEN TABLET 10MG/20M G	5051/23T	WIN MEDICA PHARMACEU TICAL 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/10M G	ZATEVEN TABLET 10MG/10M G	5052/23T	WIN MEDICA PHARMACEU TICAL 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/40M G	ZATEVEN TABLET 10MG/40M G	5050/23T	WIN MEDICA PHARMACEU TICAL 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 SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 15MCG/DO SE	INFLUVAC SUB-UNIT TETRA SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 15MCG/DO SE	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
FLUDEOXY GLUCOSE (18F) GE HEALTHCA RE SOLUTION FOR INJECTION 250MBQ/M L	FLUDEOXY GLUCOSE (18F) GE HEALTHCA RE SOLUTION FOR INJECTION 250MBQ/M L	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

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				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
COPAXON	COPAXON			B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY
E	E			CHANGES - FINISHED PRODUCT -
SOLUTION	SOLUTION			Manufacture - Change to importer,
FOR	FOR			batch release arrangements and quality
INJECTION	INJECTION			control testing of the finished product -
IN	IN			Replacement or addition of a
PREFILLED	PREFILLED			manufacturer responsible for
SYRINGE	SYRINGE			importation and/or batch release - Not
20MG/ML	20MG/ML	6214/23T, 6215/23T	TEVA GMBH	including batch control/testing
COPAXON	COPAXON			B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY
E	E			CHANGES - FINISHED PRODUCT -
SOLUTION	SOLUTION			Manufacture - Change to importer,
FOR	FOR			batch release arrangements and quality
INJECTION	INJECTION			control testing of the finished product -
IN	IN			Replacement or addition of a
PREFILLED	PREFILLED			manufacturer responsible for
SYRINGE	SYRINGE	6040/00T 0040/00T		importation and/or batch release - Not
40MG/ML PLENDIL	40MG/ML PLENDIL	6212/23T, 6213/23T	TEVA GMBH	including batch control/testing
TABLET,	TABLET,			
PROLONG	PROLONG			
ED-	ED-			
RELEASE	RELEASE		ASTRAZENEC	A.z A.z - ADMINISTRATIVE
5MG	5MG	5717/23T	A AB	CHANGES - Other variation
PLENDIL	PLENDIL			
TABLET,	TABLET,			
PROLONG	PROLONG			
ED-	ED-			
RELEASE	RELEASE	5716/22T		A.z A.z - ADMINISTRATIVE
10MG PLENDIL	10MG PLENDIL	5716/23T	A AB	CHANGES - Other variation
TABLET,	TABLET,			
PROLONG	PROLONG			
ED-	ED-			
RELEASE	RELEASE		ASTRAZENEC	A.z A.z - ADMINISTRATIVE
2.5MG	2.5MG	5718/23T	AAB	CHANGES - 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
MEDOLIN	MEDOLIN			change(s) for which no new additional
TABLET	TABLET		MEDOCHEMIE	data is required to be submitted by the
4MG	4MG	7139/23T	LTD	MAH
			1	C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar medicinal products following
MEDOLIN	MEDOLIN			assessment of the same change for the
TABLET	TABLET		MEDOCHEMIE	reference product - Implementation of
2MG	2MG	7140/23T	LTD	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, DISPERSIB LE 20MG	FELDENE TABLET, DISPERSIB LE 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
VALGANCI CLOVIR ACCORD TABLET, FILM COATED 450MG	VALGANCI CLOVIR 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

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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
CIPROFLO XACIN KABI SOLUTION FOR INFUSION 2MG/ML(40 0MG/200ML)	CIPROFLO XACIN KABI SOLUTION FOR INFUSION 2MG/ML(40 0MG/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
CIPROFLO XACIN KABI SOLUTION FOR INFUSION 2MG/ML(20 0MG/100ML)	CIPROFLO XACIN KABI SOLUTION FOR INFUSION 2MG/ML(20 0MG/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
MONTELU KAST ACCORD TABLET, CHEWABL E 4MG	MONTELU KAST ACCORD TABLET, CHEWABL E 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
MONTELU KAST ACCORD TABLET, CHEWABL E 5MG	MONTELU KAST ACCORD TABLET, CHEWABL E 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
HEMAFER ORAL DROPS SOLUTION 50MG/ML	HEMAFER ORAL DROPS SOLUTION 50MG/ML	8012/23T, 8013/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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
	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
PLASMA- PLASMA-	substance (where specified in the
LYTE 148 LYTE 148 (PH 7.4) (PH 7.4)	technical dossier) where no Ph. Eur. Certificate of Suitability is part of the
SOLUTION SOLUTION	approved dossier; or a manufacturer of
FOR FOR BAXTE	
INFUSION INFUSION 7879/23T (HELLA	S) EPE technical dossier)
	B.I.a.5.a B.I.a.5.a - QUALITY CHANGES - ACTIVE SUBSTANCE -
FLUARIX FLUARIX	Manufacture - Changes to the active
TETRA TETRA	substance of a seasonal, prepandemic
SUSPENSI SUSPENSI ON FOR GLAXO	SMITH influenza - Replacement of the strain(s)
INJECTION INJECTION KLINE	in a seasonal, prepandemic or a
15MCG/0.5 15MCG/0.5 BIOLOG	
ML ML 5897/23T SA	influenza
APIXABAN APIXABAN FARMAPR WIN ME	EDICA
OJECTS OJECTS PHARM	IACEU
TABLET, TABLET, TICAL S	
FILM FILM (TRADII COATED COATED WIN ME	
COATEDCOATEDWIN ME2.5MG2.5MG4546/23TS.A.)	CHANGES - Other variation
APIXABAN APIXABAN	
FARMAPR FARMAPR WIN ME	
OJECTS OJECTS PHARM TABLET, TABLET, TICAL S	
FILM FILM (TRADI	
COATED COATED WIN ME	
5MG 5MG 4545/23T S.A.)	CHANGES - Other variation B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY
	CHANGES - FINISHED PRODUCT -
	Container closure system - Change in
HYDROCO HYDROCO RTISONE RTISONE	pack size of the finished product -
RTISONE RTISONE ACTIVASE ACTIVASE	Change in the number of units (e.g. ASE tablets, ampoules, etc.) in a pack -
TABLET TABLET PHARM	
10MG 10MG 9240/22T TICALS	LTD approved pack sizes
	B.II.e.5.a.1 B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT -
	Container closure system - Change in
HYDROCO HYDROCO	pack size of the finished product -
	Change in the number of units (e.g.
ACTIVASE ACTIVASE ACTIVA TABLET TABLET PHARM	
20MG 20MG 9239/22T TICALS	LTD approved pack sizes
	C.I z) Changes (Safety/Efficacy) to
	Human and Veterinary Medicinal Products Other variation
HYDROCO HYDROCO	C.I.z C.I.z - SAFETY, EFFICACY,
RTISONE RTISONE	PHARMACOVIGILANCE CHANGES -
ACTIVASE ACTIVASE ACTIVA TABLET TABLET PHARM	
TABLETPHARM10MG10MG7760/20TTICALS	
	C.I z) Changes (Safety/Efficacy) to
HYDROCO HYDROCO	Human and Veterinary Medicinal
RTISONE RTISONE ACTIVASE ACTIVASE	Products Other variation ASE C.I.z C.I.z - SAFETY, EFFICACY,
TABLET TABLET PHARM	
20MG 20MG 7759/20T TICALS	LTD HUMAN AND VETERINARY

				MEDICINAL PRODUCTS - Other
				variation
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE			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
4000IU	4000IU	9367/22T, 1133/23T	VENIPHARM	variation C.I.2.b C.I.2.b - SAFETY, EFFICACY,
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 2000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 2000IU	9366/22T, 1134/23T	VENIPHARM	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling 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
200010	200010	9300/221, 1134/231	VENIPHARM	C.I.2.b C.I.2.b - SAFETY, EFFICACY,
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 6000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 6000IU	9370/22T, 1137/23T	VENIPHARM	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling 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
				C.I.2.b C.I.2.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 10000IU	LEDRAXEN SOLUTION FOR INJECTION IN PREFILLED SYRINGE 10000IU	9368/22T, 1135/23T	VENIPHARM	HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling 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

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				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
				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
LEDRAXEN	LEDRAXEN			substantiated by new additional data to
SOLUTION	SOLUTION			be submitted by the MAH (e.g.
FOR	FOR			comparability) C.I.z C.I.z - SAFETY, EFFICACY,
INJECTION IN	INJECTION			PHARMACOVIGILANCE CHANGES -
PREFILLED	PREFILLED			HUMAN AND VETERINARY
SYRINGE	SYRINGE			MEDICINAL PRODUCTS - Other
8000IU	8000IU	9369/22T, 1136/23T	VENIPHARM	variation
				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
LOSARTAN	LOSARTAN			finished product - Secondary packaging
/HYDROCH				
LOROTHIA ZIDE KRKA	LOROTHIA ZIDE KRKA			B.II.b.1.b B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT -
TABLET,	TABLET,			Manufacture - Replacement or addition
FILM	FILM			of a manufacturing site for part or all of
COATED	COATED			the manufacturing process of the
50MG/12.5	50MG/12.5	70 45 (007, 70 40 (007	KRKA D.D.	finished product - Primary packaging
MG	MG	7345/23T, 7346/23T	NOVO MESTO	site B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
				the manufacturing process of the active
				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
LIPITOR	LIPITOR			of Suitability is part of the approved
TABLET,	TABLET,			dossier - Changes to quality control
FILM COATED	FILM COATED		VIATRIS	testing arrangements for the active substance-replacement or addition of a
10MG	10MG	7337/23T, 7338/23T	HELLAS LTD	site
LIPITOR	LIPITOR		VIATRIS	B.III.1.a.3 B.III.1.a.3 - QUALITY
TABLET,	TABLET,	7335/23T, 7336/23T	HELLAS LTD	CHANGES - CEP/TSE/MONOGRAPHS

				Outomission of a new and the UDI
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	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active 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	ZARATOR TABLET, FILM COATED		UPJOHN	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active 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
20MG	20MG	7329/23T, 7330/23T	HELLAS LTD	site B.III.1.a.3 B.III.1.a.3 - QUALITY
ZARATOR TABLET, FILM COATED 40MG	ZARATOR TABLET, FILM COATED 40MG	7327/23T, 7328/23T	UPJOHN HELLAS LTD	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (replacement or addition) 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 C.I.z C.I.z - SAFETY, EFFICACY,
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

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				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, CHEWABL E 20MG	LIPITOR TABLET, CHEWABL E 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, CHEWABL E 5MG	LIPITOR TABLET, CHEWABL E 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, CHEWABL E 40MG	LIPITOR TABLET, CHEWABL E 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

1	MG	5764/23T	RAFARM S.A.	of the active substance supported by an ASMF B.I.a.1.b B.I.a.1.b - QUALITY
CINACALC CIN ET/RAFAR ET/ M TABLET, M T FILM FIL	NACALC /RAFAR TABLET, _M DATED			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
TABLET, TAI FILM FIL COATED CO	RATOR BLET, M DATED MG	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
TABLET, TAI CHEWABL CH	PITOR BLET, IEWABL 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
TABLET,TAIFILMFILCOATEDCO	RATOR BLET, M DATED MG	2737/23T	UPJOHN HELLAS LTD	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 - Change(s) in the Summary of product 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

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				of the active substance supported by an ASMF
CINACALC ET/RAFAR M TABLET, FILM COATED 30MG	CINACALC ET/RAFAR M 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
MACROGO L 4000	MACROGO L 4000			
CASEN RECORDA TI POWDER FOR ORAL SOLUTION IN SACHET 10G	CASEN RECORDA TI POWDER FOR ORAL SOLUTION IN SACHET 10G MACROGO	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)
MACROGO L 4000 CASEN RECORDA TI POWDER FOR ORAL SOLUTION IN SACHET 4G	L 4000 CASEN RECORDA TI 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
				B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in
ROSUVAST	ROSUVAST			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 -
ATIN ACCORD TABLET, FILM COATED 10MG	ATIN ACCORD TABLET, FILM COATED 10MG	6604/22T 6605/22T	ACCORD HEALTHCARE S.L.U	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)
		6604/23T, 6605/23T	3.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
ROSUVAST ATIN ACCORD TABLET, FILM COATED 40MG	ROSUVAST ATIN ACCORD TABLET, FILM COATED 40MG	6600/23T, 6601/23T	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)
ROSUVAST ATIN ACCORD TABLET, FILM COATED 20MG	ROSUVAST ATIN 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)
ROSUVAST ATIN ACCORD TABLET, FILM COATED 5MG	ROSUVAST ATIN 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)

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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/850M G	VIMETSO TABLET, FILM COATED 50MG/850M G	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)
CITRAFLEE T POWDER FOR ORAL SOLUTION	CITRAFLEE T 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 SUSPENSI ON FOR SUSPENSI ON FOR INJECTION	PENTAXIM POWDER AND SUSPENSI ON FOR SUSPENSI ON FOR INJECTION	6668/22T	SANOFI PASTEUR.	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
TETRAXIM SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	TETRAXIM SUSPENSI ON 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 SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	TETRAXIM SUSPENSI ON 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 PHARMACEU TICAL S.A. (TRADING AS	C.I.11.z C.I.11.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or

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			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 PHARMACEU TICAL 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)
LEVOFLOX ACIN KABI SOLUTION FOR INFUSION 5MG/ML	LEVOFLOX ACIN 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
MYCOPHE NOLATE MOFETIL ACCORD TABLET, FILM COATED 500MG	MYCOPHE NOLATE 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
ROSUVAST ATIN ACCORD TABLET, FILM COATED 5MG	ROSUVAST ATIN 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
ROSUVAST ATIN ACCORD TABLET, FILM COATED 10MG	ROSUVAST ATIN 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
ROSUVAST ATIN ACCORD TABLET, FILM COATED 20MG	ROSUVAST ATIN 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

ROSUVAST	ROSUVAST			
ATIN	ATIN			B.II.e.7.b B.II.e.7.b - QUALITY
ACCORD	ACCORD			CHANGES - FINISHED PRODUCT -
TABLET, FILM	TABLET, FILM		ACCORD	Container closure system - Change in supplier of packaging components or
COATED	COATED		HEALTHCARE	devices (when mentioned in the dossier)
40MG	40MG	6608/23T, 6609/23T	S.L.U	- Replacement or addition of a supplier
				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
ALBUREX	ALBUREX			B.II.b.2.b B.II.b.2.b - QUALITY
20	20			CHANGES - FINISHED PRODUCT -
SOLUTION FOR	SOLUTION FOR	1196/23T, 1197/23T,		Manufacture - Change to importer, batch release arrangements and quality
INFUSION	INFUSION	1198/23T, 1199/23T,	CSL BEHRING	control testing of the finished product -
200G/L	200G/L	1200/23T	GMBH	Replacement or addition C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
BREXIN	BREXIN		CHIESI	Characteristics, Labelling or Package
TABLET	TABLET		HELLAS	Leaflet due to new quality, preclinical,
20MG	20MG	6917/23T	A.E.B.E.	clinical or pharmacovigilance data B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
VIMETSO TABLET,	VIMETSO TABLET,			the manufacturing process of the active substance For an excipient - European
FILM	FILM			Pharmacopoeial Certificate of Suitability
COATED 50MG/1000	COATED 50MG/1000		TAD PHARMA	to the relevant Ph. Eur. Monograph -
50MG/1000 MG	MG	6452/23T	GMBH	Updated certificate from an already approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
VIMETSO	VIMETSO			of Ph. Eur. certificate of suitability: For
TABLET,	TABLET,			an active substance For a starting material/reagent/intermediate used in
FIL M				
FILM COATED	FILM COATED			the manufacturing process of the active
		6453/23T	TAD PHARMA GMBH	

AMOXIL CAPSULE, HARD 500MGAMOXIL 4708/23T, 4709/23TGLAXOSMITH (IRELAND)to the relevant Ph. Eur. Monog Updated certificate from an all approved manufacturerB.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PROI Control of excipients - Change procedure for an excipient - O changes to a test procedure (i replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PROI Control of excipients - Change procedure for an excipient - O changes to a test procedure (i replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PROI Control of excipients - Change procedure for an excipient - M changes to an approved test procedure for an excipient - M changes to an approved test procedure	ready Y DUCT - e in test tther
AMOXIL AMOXIL AMOXIL GLAXOSMITH GLAXOSMITH CAPSULE, CAPSULE, HARD 4708/23T, 4709/23T GLAXOSMITH Changes to an excipients - Change Double Finite Finite Finite Finite Finite AMOXIL AMOXIL CAPSULE, CAPSULE, Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite Finite <td< td=""><td>Y DUCT - e in test other</td></td<>	Y DUCT - e in test other
AMOXIL CAPSULE, HARD 500MGAMOXIL 4708/23T, 4709/23TB.II.c.2.d B.II.c.2.d - QUALITY CHANGES - FINISHED PROI Control of excipients - Change procedure for an excipient - O changes to a test procedure (i replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PROI Control of excipients - Change procedure for an excipient - O changes to a test procedure (i replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PROI Control of excipients - Change procedure for an excipient - M changes to an approved test procedure for B.II.b.3.z B.II.b.3.z - QUALITY	DUCT - e in test other
AMOXILAMOXILCHANGES - FINISHED PROD Control of excipients - Change procedure for an excipient - O changes to a test procedure (i replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PROD 	DUCT - e in test other
AMOXILAMOXILControl of excipients - Change procedure for an excipient - O changes to a test procedure (i replacement or addition) B.II.c.2.a B.II.c.2.a - QUALITY CHANGES - FINISHED PROD Control of excipients - Change 	e in test Ither
AMOXIL AMOXIL GLAXOSMITH procedure for an excipient - O AMOXIL AMOXIL GLAXOSMITH B.II.c.2.a B.II.c.2.a - QUALITY CAPSULE, CAPSULE, KLINE Changes to a test procedure (i HARD HARD FINISHED PROD Control of excipients - Change 500MG 500MG 4708/23T, 4709/23T LIMITED changes to an approved test p	ther
AMOXIL AMOXIL GLAXOSMITH B.II.c.2.a B.II.c.2.a - QUALITY AMOXIL GLAXOSMITH B.II.c.2.a B.II.c.2.a - QUALITY CAPSULE, CAPSULE, KLINE HARD HARD FINISHED PROD 500MG 500MG 4708/23T, 4709/23T	
AMOXIL AMOXIL GLAXOSMITH replacement or addition) AMOXIL AMOXIL GLAXOSMITH B.II.c.2.a B.II.c.2.a - QUALITY CAPSULE, CAPSULE, KLINE Changes - FINISHED PROD HARD HARD (IRELAND) procedure for an excipient - M 500MG 500MG 4708/23T, 4709/23T LIMITED B.II.b.3.z B.II.b.3.z - QUALITY	including
AMOXIL CAPSULE, HARD 500MGAMOXIL 	
AMOXIL AMOXIL GLAXOSMITH CHANGES - FINISHED PROD CAPSULE, CAPSULE, KLINE Control of excipients - Change HARD HARD (IRELAND) procedure for an excipient - M 500MG 500MG 4708/23T, 4709/23T LIMITED changes to an approved test p B.II.b.3.z B.II.b.3.z - QUALITY B.II.b.3.z - QUALITY	
CAPSULE, HARDCAPSULE, HARDKLINE (IRELAND) LIMITEDControl of excipients - Change procedure for an excipient - M changes to an approved test p500MG500MG4708/23T, 4709/23TLIMITEDchanges to an approved test pB.II.b.3.z B.II.b.3.z - QUALITY	
HARD HARD (IRELAND) procedure for an excipient - M 500MG 500MG 4708/23T, 4709/23T LIMITED changes to an approved test p B.II.b.3.z B.II.b.3.z - QUALITY	
500MG 500MG 4708/23T, 4709/23T LIMITED changes to an approved test p B.II.b.3.z B.II.b.3.z - QUALITY B.II.b.3.z B.II.b.3.z - QUALITY B.II.b.3.z B.II.b.3.z - QUALITY	
B.II.b.3.z B.II.b.3.z - QUALIT	
I CHANGES - FINISHED PROF	
	JUCI -
ROSUVAD ROSUVAD Manufacture - Change in the	
OR OR manufacturing process of the	
TABLET, TABLET, product, including an intermed	
FILM FILM in the manufacture of the finish	
COATED COATED TAD PHARMA product - Change in the holdin	ig time of
10MG 10MG 6536/23T GMBH an intermediate	
B.II.b.3.z B.II.b.3.z - QUALIT	
CHANGES - FINISHED PROL	JUCI -
ROSUVAD ROSUVAD Manufacture - Change in the	<i>c</i> · · · ·
OR OR manufacturing process of the	
TABLET, TABLET, product, including an intermed	
FILM FILM in the manufacture of the finish	
COATED COATED TAD PHARMA product - Change in the holdin	ig time of
20MG 20MG 6535/23T GMBH an intermediate B.II.b.3.z B.II.b.3.z - QUALITY B.II.b.3.z - QUALITY B.II.b.3.z - QUALITY	<u></u>
CHANGES - FINISHED PROL	
	JUCT -
ROSUVAD ROSUVAD OR OR Manufacture - Change in the manufacturing process of the	finished
TABLET, TABLET, product, including an intermed	
FILM FILM in the manufacture of the finis	
COATED COATED TAD PHARMA product - Change in the holdin	
5MG 5MG 6537/23T GMBH an intermediate	ig time of
PALIPERID PALIPERID	
ONE/TEVA ONE/TEVA	
PHARMA PHARMA B.II.b.3.a B.II.b.3.a - QUALIT	Y
PROLONG PROLONG CHANGES - FINISHED PROL	
ED ED Manufacture - Change in the	
RELEASE RELEASE manufacturing process of the	finished
SUSPENSI SUSPENSI product, including an intermed	
ON FOR ON FOR In the manufacture of the finish	
INJECTION INJECTION TEVA product - Minor change in the	
100MG 100MG 7136/23T PHARMA BV manufacturing process	
PALIPERID PALIPERID	
ONE/TEVA ONE/TEVA	
PHARMA PHARMA B.II.b.3.a B.II.b.3.a - QUALIT	Y
PROLONG PROLONG CHANGES - FINISHED PROL	JUCT -
ED ED Manufacture - Change in the	
RELEASE RELEASE manufacturing process of the	
SUSPENSI SUSPENSI product, including an intermed	diate used
ON FOR ON FOR in the manufacture of the finish	
INJECTION INJECTION TEVA product - Minor change in the	
150MG 150MG 7135/23T PHARMA BV manufacturing process	
PALIPERID PALIPERID	
ONE/TEVA ONE/TEVA	
PHARMA PHARMA B.II.b.3.a B.II.b.3.a - QUALIT	
PROLONG PROLONG CHANGES - FINISHED PROL	JUCT -
ED ED Manufacture - Change in the	
RELEASE RELEASE manufacturing process of the	
	liate used
SUSPENSI SUSPENSI product, including an intermed	
SUSPENSI SUSPENSI product, including an intermed in the manufacture of the finish	hed
SUSPENSI SUSPENSI product, including an intermed	hed

GEMCITABI NE	GEMCITABI NE			A.5.b A.5.b - ADMINISTRATIVE
ACCORD	ACCORD			CHANGES - Change in the name
POWDER	POWDER			and/or address of a
FOR	FOR			manufacturer/importer of the finished
SOLUTION	SOLUTION			product (including batch release or
FOR	FOR			quality control testing sites) - The
INFUSION	INFUSION		ACCORD	activities for which the
200MG/VIA	200MG/VIA		HEALTHCARE	manufacturer/importer is responsible do
L	L	7794/23T	S.L.U	not include batch release
GEMCITABI	GEMCITABI			A.5.b A.5.b - ADMINISTRATIVE
NE	NE			CHANGES - Change in the name
ACCORD	ACCORD			and/or address of a
POWDER	POWDER			manufacturer/importer of the finished
FOR	FOR			product (including batch release or
SOLUTION	SOLUTION			quality control testing sites) - The
FOR	FOR		ACCORD	activities for which the
	INFUSION	7702/00T	HEALTHCARE	manufacturer/importer is responsible do
1G/VIAL	1G/VIAL	7793/23T	S.L.U	not include batch release
				B.I.b.1.c B.I.b.1.c - QUALITY
LAMIVUDIN	LAMIVUDIN			CHANGES - ACTIVE SUBSTANCE -
E/ZIDOVUD	E/ZIDOVUD			Control of active substance - Change in the specification parameters and/or
INE	INE			limits of an active substance, starting
ACCORD	ACCORD			material / intermediate / reagent used in
TABLET,	TABLET,			the manufacturing process of the active
FILM	FILM			substance - Addition of a new
COATED	COATED		ACCORD	specification parameter to the
150MG/300	150MG/300		HEALTHCARE	specification with its corresponding test
MG	MG	7973/22T	S.L.U	method
SITAGLIPTI	SITAGLIPTI			B.II.e.2.c B.II.e.2.c - QUALITY
N/METFOR	N/METFOR			CHANGES - FINISHED PRODUCT -
MIN APC	MIN APC			Container closure system - Change in
MODIFIED-	MODIFIED-			the specification parameters and/or
RELEASE	RELEASE			limits of the immediate packaging of the
TABLET	TABLET		APC	finished product - Deletion of a non-
50MG/500M	50MG/500M	7005/00T 7000/00T	INSTYTUT SP.	significant specification parameter (e.g.
G SITAGLIPTI	G SITAGLIPTI	7325/23T, 7326/23T	Z.O.O.	deletion of an obsolete parameter) B.II.e.2.c B.II.e.2.c - QUALITY
N/METFOR	N/METFOR			CHANGES - FINISHED PRODUCT -
MIN APC	MIN APC			Container closure system - Change in
MODIFIED-	MODIFIED-			the specification parameters and/or
RELEASE	RELEASE			limits of the immediate packaging of the
TABLET	TABLET		APC	finished product - Deletion of a non-
50MG/1000	50MG/1000		INSTYTUT SP.	significant specification parameter (e.g.
MG	MG	7323/23T, 7324/23T	Z.O.O.	deletion of an obsolete parameter)
SITAGLIPTI	SITAGLIPTI			B.II.e.2.c B.II.e.2.c - QUALITY
N/METFOR	N/METFOR			CHANGES - FINISHED PRODUCT -
MIN APC	MIN APC			Container closure system - Change in
MODIFIED-	MODIFIED-			the specification parameters and/or
RELEASE	RELEASE			limits of the immediate packaging of the
TABLET	TABLET		APC	finished product - Deletion of a non-
100MG/100	100MG/100	7004/007 7000/007	INSTYTUT SP.	significant specification parameter (e.g.
OMG	0MG	7321/23T, 7322/23T	Z.O.O.	deletion of an obsolete parameter)
				B.V.a.1.d B.V.a.1.d - QUALITY
				CHANGES - Changes to a marketing
				authorisation resulting from other
				regulatory procedures - PMF/VAMF -
				Inclusion of a new, updated or amended
				Plasma Master File in the marketing authorisation dossier of a medicinal
NANOGAM	NANOGAM		PROTHYA	product. (PMF 2nd step procedure) -
SOLUTION	SOLUTION		BIOSOLUTION	Inclusion of an updated/amended
			S	Plasma Master File when changes do
FOR	FOR			
FOR INFUSION	FOR INFUSION			not affect the properties of the finished
INFUSION	INFUSION	6756/23T	NETHERLAND S B.V.	not affect the properties of the finished product
	INFUSION 100MG/ML	6756/23T	S B.V.	
INFUSION 100MG/ML	INFUSION	6756/23T		
INFUSION 100MG/ML LINEZID	INFUSION 100MG/ML LINEZID	6756/23T 6216/23T	S B.V. SAPIENS	product

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 INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG	SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG	6618/23T	GLAXOSMITH KLINE 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 INHALATIO N POWDER, PRE- DISPENSE D 50MCG/500 MCG	SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/500 MCG	6616/23T	GLAXOSMITH KLINE 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 INHALATIO N POWDER, PRE- DISPENSE D 50MCG/250 MCG	SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/250 MCG	6617/23T	GLAXOSMITH KLINE 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 INHALATIO N 2.5MCG/PU FF SPIRIVA	SPIRIVA RESPIMAT SOLUTION FOR INHALATIO N 2.5MCG/PU FF SPIRIVA	6475/23T	BOEHRINGER INGELHEIM INTERNATION AL 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 A.5.b A.5.b - ADMINISTRATIVE
INHALATIO N	INHALATIO N	6474/23T	BOEHRINGER INGELHEIM	CHANGES - Change in the name and/or address of a

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POWDER, HARD CAPSULE 18MCG	POWDER, HARD CAPSULE 18MCG		INTERNATION AL 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 INHALATIO N	STRIVERDI RESPIMAT SOLUTION FOR INHALATIO N	6476/23T	BOEHRINGER INGELHEIM INTERNATION AL 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 INHALATIO N (2.5MCG/2. 5MCG)/DO SE	SPIOLTO RESPIMAT SOLUTION FOR INHALATIO N (2.5MCG/2. 5MCG)/DO SE	6472/23T	BOEHRINGER INGELHEIM INTERNATION AL 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 INHALATIO N	YANIMO RESPIMAT SOLUTION FOR INHALATIO N	6473/23T	BOEHRINGER INGELHEIM INTERNATION AL 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
PIPERACIL LIN/TAZOB ACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G PIPERACIL LIN/TAZOB	PIPERACIL LIN/TAZOB ACTAM KABI POWDER FOR SOLUTION FOR INFUSION 2G/0.25G PIPERACIL LIN/TAZOB ACTAM	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 B.II.b.5.c B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT -
ACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	ACTAM KABI POWDER FOR SOLUTION FOR INFUSION 4G/0.5G	6997/23T, 6998/23T, 6999/23T, 7000/23T	FRESENIUS KABI HELLAS A.E.	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

VARIVAX POWDER	VARIVAX POWDER			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 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
AND	AND			active substance, intermediate or
SOLVENT FOR	SOLVENT FOR			finished product, packaging site, manufacturer responsible for batch
SUSPENSI ON FOR	SUSPENSI ON FOR		MERCK	release, site where batch control takes place, or supplier of a starting material,
INJECTION 1350 PFU	INJECTION 1350 PFU	6670/23T, 6671/23T	SHARP & DOHME BV	reagent or excipient (when mentioned in the dossier)*
MICROLAX RECTAL SOLUTION (0.45G/0.06 45G/4.465G)/DOSE	MICROLAX RECTAL SOLUTION (0.45G/0.06 45G/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 TRANSDER MAL GEL 16.2 MG/G	TESTOGEL TRANSDER MAL GEL 16.2 MG/G	8705/22T, 8706/22T, 8707/22T	LABORATOIR ES BESINS INTERNATION AL	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 CUTANEO US FOAM 5% W/W	REGAINE WOMEN'S FOAM CUTANEO US 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

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				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	MUNDIPHARM A PHARMACEU TICALS 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
OXYCONTI N TABLET, PROLONG ED- RELEASE 80MG	OXYCONTI N TABLET, PROLONG ED- RELEASE 80MG	3606/22T	MUNDIPHARM A PHARMACEU TICALS 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
OXYCONTI N TABLET, PROLONG ED- RELEASE 40MG	OXYCONTI N TABLET, PROLONG ED- RELEASE 40MG	3605/22T	MUNDIPHARM A PHARMACEU TICALS 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 C.I.3.b C.I.3.b - SAFETY, EFFICACY,
OXYNORM CAPSULE,	OXYNORM CAPSULE,	3608/22T	MUNDIPHARM A	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

HARD	HARD		PHARMACEU	MEDICINAL PRODUCTS - Change(s)
10MG	10MG		TICALS LTD	in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR 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
				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
OXYNORM	OXYNORM			Articles 45 or 46 of Regulation
LIQUID	LIQUID		MUNDIPHARM	1901/2006 - Implementation of
ORAL	ORAL		A	change(s) which require to be further
SOLUTION	SOLUTION	2610/227	PHARMACEU	substantiated by new additional data to
5MG/5ML	5MG/5ML	3610/22T	TICALS LTD	be submitted by the MAH 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
	OXYCONTI N TABLET,			by the competent authority under Articles 45 or 46 of Regulation
N TABLET, PROLONG	PROLONG		MUNDIPHARM	1901/2006 - Implementation of
ED-	ED-		A	change(s) which require to be further
RELEASE	RELEASE		PHARMACEU	substantiated by new additional data to
20MG	20MG	3604/22T	TICALS LTD	be submitted by the MAH
				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
OXYCONTI	OXYCONTI			by the competent authority under
N TABLET, PROLONG	N TABLET, PROLONG		MUNDIPHARM	Articles 45 or 46 of Regulation 1901/2006 - Implementation of
ED-	ED-		A	change(s) which require to be further
RELEASE	RELEASE		PHARMACEU	substantiated by new additional data to
10MG	10MG	3603/22T	TICALS LTD	be submitted by the MAH
				C.I.3.b C.I.3.b - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
0.000	0.0.0.0		MUNDIPHARM	Characteristics, Labelling or Package
				Leaflet of human medicinal products intended to implement the outcome of a
CAPSULE, HARD 5MG	CAPSULE, HARD 5MG	3607/22T	PHARMACEU TICALS LTD	procedure concerning PSUR or PASS,
		0001/221		procedure concerning r SOIX of r ASS,

				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
				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,
OXYNORM	OXYNORM			or the outcome of the assessment done
SOLUTION FOR	SOLUTION FOR			by the competent authority under Articles 45 or 46 of Regulation
INJECTION	INJECTION		MUNDIPHARM	1901/2006 - Implementation of
OR	OR		A	change(s) which require to be further
INFUSION	INFUSION		PHARMACEU	substantiated by new additional data to
50MG/ML	50MG/ML	3601/22T	TICALS LTD	be submitted by the MAH
				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
OXYNORM	OXYNORM		MUNDIPHARM	1901/2006 - Implementation of
CAPSULE, HARD	CAPSULE, HARD		A PHARMACEU	change(s) which require to be further substantiated by new additional data to
20MG	20MG	3609/22T	TICALS LTD	be submitted by the MAH
				C.I.3.b C.I.3.b - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
OXYCONTI	OXYCONTI			or the outcome of the assessment done by the competent authority under
N TABLET,	N TABLET,			Articles 45 or 46 of Regulation
PROLONG	PROLONG		MUNDIPHARM	1901/2006 - Implementation of
ED-	ED-		A	change(s) which require to be further
RELEASE	RELEASE	2602/22T		substantiated by new additional data to
5MG	5MG	3602/22T	TICALS LTD	be submitted by the MAH 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
OXYNORM	OXYNORM			procedure concerning PSUR or PASS,
CONCENT				or the outcome of the assessment done
RATE ORAL	RATE		MUNDIPHARM	by the competent authority under
	ORAL		А	Articles 45 or 46 of Regulation
SOLUTION	ORAL SOLUTION		A PHARMACEU	Articles 45 or 46 of Regulation 1901/2006 - Implementation of

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				substantiated by new additional data to be submitted by the MAH
				B.II.b.5.z B.II.b.5.z - QUALITY
PHYSIONE	PHYSIONE			CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process
AL 40	AL 40			tests or limits applied during the
GLUCOSE	GLUCOSE			manufacture of the finished product -
SOLUTION	SOLUTION			Other changes
FOR PERITONE	FOR PERITONE			B.II.b.3.z B.II.b.3.z - QUALITY CHANGES - FINISHED PRODUCT -
AL	AL			Manufacture - Change in the
DIALYSIS	DIALYSIS			manufacturing process of the finished
3.86 %	3.86 %	2204/22T 2202/22T	DAVTED	product, including an intermediate used
W/V/38.6 MG/ML	W/V/38.6 MG/ML	3391/23T, 3392/23T, 4427/23T	BAXTER (HELLAS) EPE	in the manufacture of the finished product - Other changes
		1121/201		B.II.b.5.z B.II.b.5.z - QUALITY
				CHANGES - FINISHED PRODUCT -
PHYSIONE AL 40	PHYSIONE AL 40			Manufacture - Change to in-process tests or limits applied during the
GLUCOSE	GLUCOSE			manufacture of the finished product -
SOLUTION	SOLUTION			Other changes
FOR	FOR			B.II.b.3.z B.II.b.3.z - QUALITY
PERITONE AL	PERITONE AL			CHANGES - FINISHED PRODUCT - Manufacture - Change in the
DIALYSIS				manufacturing process of the finished
2.27 %	2.27 %			product, including an intermediate used
W/V/22.7 MG/ML	W/V/22.7 MG/ML	3393/23T, 3394/23T, 4428/23T	BAXTER	in the manufacture of the finished
INIG/INIL	IVIG/IVIL	4420/231	(HELLAS) EPE	product - Other changes B.II.b.5.z B.II.b.5.z - QUALITY
				CHANGES - FINISHED PRODUCT -
PHYSIONE	PHYSIONE			Manufacture - Change to in-process
AL 40 GLUCOSE	AL 40 GLUCOSE			tests or limits applied during the manufacture of the finished product -
SOLUTION	SOLUTION			Other changes
FOR	FOR			B.II.b.3.z B.II.b.3.z - QUALITY
PERITONE AL	PERITONE AL			CHANGES - FINISHED PRODUCT -
				Manufacture - Change in the manufacturing process of the finished
1.36 %	1.36 %			product, including an intermediate used
W/V/13.6	W/V/13.6	3395/23T, 3396/23T,	BAXTER	in the manufacture of the finished
MG/ML	MG/ML	4429/23T	(HELLAS) EPE	product - Other changes C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS, or the outcome of the assessment done
				by the competent authority under
ACCU-	ACCU-			Articles 45 or 46 of Regulation
THYROX ORAL	THYROX ORAL			1901/2006 - Implementation of wording agreed by the competent authority that
SOLUTION	SOLUTION			require additional minor assessment,
25MCG/5M	25MCG/5M			e.g. translations are not yet agreed
L	L	758/23T, 759/23T	GALENICA SA	upon C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
ACCU-	ACCU-			Leaflet of human medicinal products
THYROX	THYROX			intended to implement the outcome of a
ORAL SOLUTION	ORAL SOLUTION			procedure concerning PSUR or PASS, or the outcome of the assessment done
50MCG/5M	50MCG/5M			by the competent authority under
L	L	756/23T, 757/23T	GALENICA SA	Articles 45 or 46 of Regulation

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				1901/2006 - Implementation of wording agreed by the competent authority that
				require additional minor assessment,
				e.g. translations are not yet agreed
				C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of the assessment done
				by the competent authority under
ACCU- THYROX	ACCU- THYROX			Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
ORAL	ORAL			agreed by the competent authority that
SOLUTION	SOLUTION			require additional minor assessment,
100MCG/5	100MCG/5	754/007 755/007		e.g. translations are not yet agreed
ML METFORMI	ML METFORMI	754/23T, 755/23T	GALENICA SA	upon B.II.d.2.a B.II.d.2.a - QUALITY
N ACCORD	N ACCORD			CHANGES - FINISHED PRODUCT -
TABLET,	TABLET,			Control of finished product - Change in
FILM	FILM		ACCORD	test procedure for the finished product -
COATED 850MG	COATED 850MG	6821/23T	HEALTHCARE S.L.U	Minor changes to an approved test procedure
METFORMI	METFORMI		0.2.0	B.II.d.2.a B.II.d.2.a - QUALITY
N ACCORD	N ACCORD			CHANGES - FINISHED PRODUCT -
TABLET,	TABLET,			Control of finished product - Change in
FILM COATED	FILM COATED		ACCORD HEALTHCARE	test procedure for the finished product - Minor changes to an approved test
500MG	500MG	6822/23T	S.L.U	procedure
				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 -
ADACEL	ADACEL			Substantial change to, or replacement
SUSPENSI	SUSPENSI			of, a biological/ immunological/
ON FOR	ON FOR			immunochemical test method or a method using a biological reagent or
IN PRE-	IN PRE-			replacement of a biological reference
FILLED	FILLED		SANOFI	preparation not covered by an approved
SYRINGE	SYRINGE	6467/23T	PASTEUR.	
				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
INFANRIX TETRA	INFANRIX TETRA		GLAXOSMITH	suitability for an active substance/starting material/reagent/
SUSPENSI	SUSPENSI		KLINE	intermediate/or excipient - Updated
ON FOR	ON FOR		BIOLOGICALS	certificate from an already approved
INJECTION	INJECTION	7163/23T	SA	manufacturer
BOOSTRIX SUSPENSI	BOOSTRIX SUSPENSI			B.II.d.2.d B.II.d.2.d - QUALITY
ON FOR	ON FOR			CHANGES - FINISHED PRODUCT -
INJECTION	INJECTION		GLAXOSMITH	Control of finished product - Change in
IN PRE-	IN PRE-		KLINE BIOLOGICALS	test procedure for the finished product -
FILLED SYRINGE	FILLED SYRINGE	5785/23T	SA	Other changes to a test procedure (including replacement or addition)
FERANT	FERANT			B.I.z B.I.z - QUALITY CHANGES -
SOLUTION	SOLUTION		MEDOCHEMIE	ACTIVE SUBSTANCE - Substantial
FOR	FOR	7902/22T	LTD	updates to Mod. 3.2.S or the ASMF

INJECTION	INJECTION			
50MCG/ML	50MCG/ML			
AMINOPLA SMAL B. BRAUN 10% E SOLUTION FOR INFUSION 100G/L	AMINOPLA SMAL 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 SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 160 ANTIGEN UNITS/0.5M L	AVAXIM SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 160 ANTIGEN UNITS/0.5M L	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
SOLIFENA CIN ACCORD TABLET, FILM COATED 10MG	SOLIFENA CIN 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
SOLIFENA CIN ACCORD TABLET, FILM COATED 5MG	SOLIFENA CIN 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

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				substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ADACEL SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	ADACEL SUSPENSI ON 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/60M G AND 500MG/25M G	HEXAFLU DAY & NIGHT TABLET 500MG/60M G AND 500MG/25M G	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 SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	ADACEL SUSPENSI ON 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
EFAVIREN Z AUROBIND O TABLET, FILM COATED 600MG	EFAVIREN Z AUROBIND O 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 SUSPENSI ON FOR INJECTION IN PRE-	ADACEL SUSPENSI ON 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

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FILLED SYRINGE	FILLED SYRINGE			in the manufacture of the finished product - Minor change in the manufacturing process
ADACEL SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	ADACEL SUSPENSI ON 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 SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	ADACEL SUSPENSI ON 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 SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	ADACEL SUSPENSI ON 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 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 A.7 A.7 - ADMINISTRATIVE
CYTARABI NE ACCORD SOLUTION FOR INJECTION OR INFUSION 100MG/ML	CYTARABI NE ACCORD SOLUTION FOR INJECTION OR INFUSION 100MG/ML	7207/23T	ACCORD HEALTHCARE S.L.U	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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	ALBUMAN SOLUTION FOR INFUSION 40G/L ALBUMAN SOLUTION FOR	6876/23T 6875/23T	PROTHYA BIOSOLUTION S NETHERLAND S B.V. PROTHYA BIOSOLUTION S	B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF - Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other

INFUSION	INFUSION		NETHERLAND	regulatory procedures - PMF/VAMF -
200G/L	200G/L		S B.V.	Inclusion of a new, updated or amended
				Plasma Master File in the marketing
				authorisation dossier of a medicinal product. (PMF 2nd step procedure) -
				Inclusion of an updated/amended
				Plasma Master File when changes do
				not affect the properties of the finished product
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				 Submission of a new 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
ZIRCOS	ZIRCOS			CHANGES - FINISHED PRODUCT -
TABLET,	TABLET,			Control of finished product - Change in
FILM COATED	FILM COATED	1238/23T, 1239/23T,	NASSINGTON	the specification parameters and/or limits of the finished product -
10MG	10MG	1240/23T, 1241/23T	LTD	Tightening of specification limits
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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 -
TABLET, FILM	TABLET, FILM			Control of finished product - Change in the specification parameters and/or
COATED	COATED	1242/23T, 1243/23T,	NASSINGTON	limits of the finished product -
5MG	5MG	1244/23T, 1245/23T	LTD	Tightening of specification limits B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
ZIRCOS	ZIRCOS			- Submission of a new or updated Ph.
TABLET, FILM	TABLET, FILM			Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
COATED	COATED	1234/23T, 1235/23T,	NASSINGTON	an active substance For a starting
20MG	20MG	1236/23T, 1237/23T	LTD	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	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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 A.7 A.7 - ADMINISTRATIVE
ZIRCOS TABLET, FILM	ZIRCOS TABLET, FILM	7787/23T, 7788/23T	NASSINGTON LTD	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product,

COATER				nookoging oito monufacture
COATED 20MG	COATED 20MG			packaging site, manufacturer responsible for batch release, site
2000				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
				A.7 Deletion of manufacturing sites for
				an active substance, intermediate or
PANADOL	PANADOL		GLAXOSMITH	finished product, packaging site, manufacturer responsible for batch
COLD &	COLD &		KLINE	release, site where batch control takes
FLU &	FLU &		ΚΑΤΑΝΑΛΩΤΙ	place, or supplier of a starting material,
COUGH	COUGH		ΚΑ ΠΡΟΙΟΝΤΑ	reagent or excipient (when mentioned in
POWDER FOR ORAL	POWDER		ΥΓΕΙΑΣ ΕΛΛΑΣ	the dossier)*
SOLUTION	FOR ORAL SOLUTION		ΑΝΩΝΥΜΗ	B.III.1 a) 2. Updated certificate from an already approved manufacturer
1000MG/20	1000MG/20		ETAIPEIA	A.5 a) The activities for which the
0MG/12.2M	0MG/12.2M	3221/20T, 3222/20T,	(GSK CH	manufacturer/importer is responsible
G	G	3223/20T	ΕΛΛΑΣ ΑΕ)	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
			GLAXOSMITH	manufacturer/importer is responsible do not include batch release
			KLINE	A.7 A.7 - ADMINISTRATIVE CHANGES
PANADOL	PANADOL		ΚΑΤΑΝΑΛΩΤΙ	- Deletion of manufacturing sites for an
COLD &	COLD &		ΚΑ ΠΡΟΙΟΝΤΑ	active substance, intermediate or
FLU &	FLU & COUGH		ΥΓΕΙΑΣ ΕΛΛΑΣ	finished product, packaging site,
COUGH CAPSULE,	CAPSULE,		ΑΝΩΝΥΜΗ	manufacturer responsible for batch release, site where batch control takes
HARD	HARD		ETAIPEIA	place, or supplier of a starting material,
500MG/100	500MG/100	5599/23T, 5600/23T,	(GSK CH	reagent or excipient (when mentioned in
MG/6.1MG	MG/6.1MG	5601/23T	ΕΛΛΑΣ ΑΕ)	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
PANADOL	PANADOL		GLAXOSMITH	manufacturer/importer is responsible do not include batch release
COLD &	COLD &		KLINE	A.7 A.7 - ADMINISTRATIVE CHANGES
FLU &	FLU &		ΚΑΤΑΝΑΛΩΤΙ	- Deletion of manufacturing sites for an
COUGH	COUGH			active substance, intermediate or
	POWDER		ΥΓΕΙΑΣ	finished product, packaging site,
FOR ORAL SOLUTION	FOR ORAL SOLUTION		ΕΛΛΑΣ ΑΝΩΝΥΜΗ	manufacturer responsible for batch release, site where batch control takes
1000MG/20	1000MG/20		ETAIPEIA	place, or supplier of a starting material,
0MG/12.2M	0MG/12.2M	5602/23T, 5603/23T,	(GSK CH	reagent or excipient (when mentioned in
G	G	5604/23T	ΕΛΛΑΣΑΕ)	the dossier)*
		7808/23T		A.7 A.7 - ADMINISTRATIVE
CAPSULE,	CAPSULE,	7808/23T	LTD	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)*
				A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance,
				intermediate or finished product, packaging site, manufacturer responsible for batch release, site
MOXILEN CAPSULE, HARD 500MG	MOXILEN CAPSULE, HARD 500MG	7807/23T	MEDOCHEMIE LTD	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
VARILRIX	VARILRIX			an active substance For a starting material/reagent/intermediate used in
POWDER AND SOLVENT	POWDER AND SOLVENT			the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of
FOR SOLUTION	FOR SOLUTION		GLAXOSMITH	suitability for an active substance/starting material/reagent/
FOR INJECTION 2000PFU	FOR INJECTION 2000PFU	7148/23T, 7149/23T	KLINE BIOLOGICALS SA	intermediate/or excipient - Updated certificate from an already approved manufacturer
				B.III.1.b.3 B.III.1.b.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
PRIORIX- TETRA	PRIORIX- TETRA			- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
	POWDER AND			an active substance For a starting material/reagent/intermediate used in
SOLVENT FOR SOLUTION	SOLVENT FOR SOLUTION			the manufacturing process of the active substance For an excipient - European Pharmacopoeial TSE Certificate of
FOR INJECTION IN PRE-	FOR INJECTION IN PRE-		GLAXOSMITH KLINE	suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated
FILLED SYRINGE	FILLED SYRINGE	7150/23T, 7151/23T	BIOLOGICALS SA	certificate from an already approved manufacturer
				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
PRIORIX	PRIORIX			an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active
POWDER & SOLVENT	POWDER & SOLVENT			substance For an excipient - European Pharmacopoeial TSE Certificate of
FOR SOL. FOR INJ. IN PRE-	FOR SOL. FOR INJ. IN PRE-		GLAXOSMITH KLINE	suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated
FILLED SYRINGE	FILLED SYRINGE	7152/23T, 7153/23T	BIOLOGICALS SA	certificate from an already approved manufacturer
LOSARTAN /HYDROCH LOROTHIA	LOSARTAN /HYDROCH LOROTHIA			C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
ZIDE KRKA TABLET, FILM	ZIDE KRKA TABLET, FILM	6182/23T, 6183/23T	KRKA D.D. NOVO MESTO	in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar

COATED	COATED			medicinal products following
100/12.5MG	100/12.5MG			assessment of the 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.
				A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing sites for an active substance,
				intermediate or finished product,
ZANERIL	ZANERIL			packaging site, manufacturer
TABLET,	TABLET,			responsible for batch release, site
FILM	FILM		RECORDATI	where batch control takes place, or
COATED	COATED		HELLAS	supplier of a starting material, reagent
10MG/10M G	10MG/10M G	7223/23T	PHARMACEU TICALS SA	or excipient (when mentioned in the dossier)*
9	9	7223/231	TICALS SA	A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
ZANERIL	ZANERIL			packaging site, manufacturer
TABLET,	TABLET,			responsible for batch release, site
FILM COATED	FILM COATED		RECORDATI HELLAS	where batch control takes place, or supplier of a starting material, reagent
20MG/10M	20MG/10M		PHARMACEU	or excipient (when mentioned in the
G	G	7222/23T	TICALS SA	dossier)*
				A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
ZANERIL TABLET,	ZANERIL TABLET,			packaging site, manufacturer responsible for batch release, site
FILM	FILM		RECORDATI	where batch control takes place, or
COATED	COATED		HELLAS	supplier of a starting material, reagent
20MG/20M	20MG/20M		PHARMACEU	or excipient (when mentioned in the
G	G	7221/23T	TICALS SA	dossier)*
			GLAXOSMITH	
			ΚLINE ΚΑΤΑΝΑΛΩΤΙ	
			ΚΑ ΠΡΟΙΟΝΤΑ	
			ΥΓΕΙΑΣ	
			ΕΛΛΑΣ	
ZOVIDUO	ZOVIDUO		ΑΝΩΝΥΜΗ	A.1 A.1 - ADMINISTRATIVE
CREAM	CREAM		ETAIPEIA	CHANGES - Change in the name
(50MG/10M	(50MG/10M	2720/22T	(GSK CH	and/or address of the marketing
G)/G	G)/G	3720/23T	EΛΛΑΣ ΑΕ) GLAXOSMITH	authorisation holder
			KLINE	
			ΚΑΤΑΝΑΛΩΤΙ	
			ΚΑ ΠΡΟΙΟΝΤΑ	
			ΥΓΕΙΑΣ	
OTRIVIN	OTRIVIN		ΕΛΛΑΣ	
				A.1 A.1 - ADMINISTRATIVE
NASAL SPRAY,	NASAL SPRAY,		ETAIPEIA (GSK CH	CHANGES - Change in the name and/or address of the marketing
SOLUTION	SOLUTION	3719/23T	ΕΛΛΑΣΑΕ)	authorisation holder
SSECTION	SOLUTION	0.10/201		

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NICORETT	NICORETT E			
E QUICKSPR AY BERRY OROMUCO SAL SPRAY, SOLUTION 1MG/SPRA Y	E QUICKSPR AY BERRY OROMUCO SAL SPRAY, SOLUTION 1MG/SPRA Y	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
CONTRAC TUBEX GEL	CONTRAC TUBEX GEL	7746/23T	MERZ PHARMACEU TICALS 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
MOXIFALO N T TABLET, FILM COATED 400MG	MOXIFALO N T TABLET, FILM COATED	1622/21T	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
400MG SUGAMMA	400MG SUGAMMA	1633/21T	DEMO S.A.	МАН
DEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	DEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	7320/23T	SAPIENS PHARMACEU TICALS 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 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
COTROVAL TABLET, FILM COATED 320/12.5MG	COTROVAL TABLET, FILM COATED 320/12.5MG	7641/23T	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
COTROVAL TABLET, FILM COATED 160/25MG	COTROVAL TABLET, FILM COATED 160/25MG	7642/23T	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

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				medicinal products following assessment of the 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 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
COTROVAL TABLET, FILM COATED 160/12.5MG	COTROVAL TABLET, FILM COATED 160/12.5MG	7643/23T	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
NOSATEL TABLET, FILM COATED 25MG	NOSATEL TABLET, FILM COATED 25MG	3731/23T	MENARINI INTERNATION AL OPERATIONS LUXEMBOUR G SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
SIMEVIN TABLET, FILM COATED 50MG/1000 MG SIMEVIN TABLET, FILM COATED 50MG/850M	SIMEVIN TABLET, FILM COATED 50MG/1000 MG SIMEVIN TABLET, FILM COATED 50MG/850M	6588/23T, 6589/23T, 6590/23T 6591/23T, 6592/23T,	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES SA UNI-PHARMA KLEON TSETIS PHARMACEU	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 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

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			LABORATORI ES 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	TAPTIQOM EYE			
EYE DROPS, SOLUTION (15MCG/5M G)/ML TAPTIQOM	DROPS, SOLUTION (15MCG/5M G)/ML TAPTIQOM	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
EYE DROPS, SOLUTION IN SINGLE- DOSE CONTAINE R (15MCG/5M G)/ML	EYE DROPS, SOLUTION IN SINGLE- DOSE CONTAINE R (15MCG/5M G)/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 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)*
DAREQ TABLET, FILM COATED 5MG ADACEL	DAREQ TABLET, FILM COATED 5MG ADACEL	5004/23T	DELORBIS PHARMACEU TICALS LTD	A.5.b Á.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the 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.IV.1.a.1 B.IV.1.a.1 - QUALITY
SUSPENSI ON FOR INJECTION IN PRE-	SUSPENSI ON FOR INJECTION IN PRE-	4977/23T	SANOFI PASTEUR.	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	FILLED			primary packaging - Device with CE
SYRINGE	SYRINGE		GLAXOSMITH	marking
ZOVIDUO CREAM (50MG/10M G)/G	ZOVIDUO CREAM (50MG/10M G)/G	5715/23T	ΚLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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
PANMIGRA N TABLET, FILM COATED 250MG/250 MG/65MG	PANMIGRA N TABLET, FILM COATED 250MG/250 MG/65MG	5712/23T	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩ ΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩ ΠΗ 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/100 MG/6.1MG	PANADOL COLD & FLU & COUGH CAPSULE, HARD 500MG/100 MG/6.1MG	5714/23T	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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 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.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND 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 PHARMACEU TICAL 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
				C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar medicinal products following
				assessment of the 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
LUCIDEL TABLET,	LUCIDEL TABLET,			MEDICINAL PRODUCTS - Change(s) in the Summary of Product
FILM	FILM		ELPEN	Characteristics, Labelling or Package
COATED	COATED		PHARMACEU	Leaflet due to new quality, preclinical,
300MG	300MG	4717/22T	TICAL CO INC	clinical or pharmacovigilance data B.II.b.5.z B.II.b.5.z - QUALITY
				CHANGES - FINISHED PRODUCT -
ADVECIT	ADVECIT			Manufacture - Change to in-process
CAPSULE,	CAPSULE,		DELORBIS PHARMACEU	tests or limits applied during the
HARD 100MG	100MG	7648/23T	TICALS LTD	Other changes
-	-			B.II.b.5.z B.II.b.5.z - QUALITY
				CHANGES - FINISHED PRODUCT -
ADVECIT CAPSULE,	ADVECIT CAPSULE,		DELORBIS	Manufacture - Change to in-process tests or limits applied during the
HARD	HARD		PHARMACEU	manufacture of the finished product -
180MG	180MG	7646/23T	TICALS LTD	
				B.II.b.5.z B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT -
ADVECIT	ADVECIT			Manufacture - Change to in-process
CAPSULE,	CAPSULE,		DELORBIS	tests or limits applied during the
HARD 140MG	HARD 140MG	7647/23T	PHARMACEU TICALS LTD	manufacture of the finished product - Other changes
				B.II.b.5.z B.II.b.5.z - QUALITY
				CHANGES - FINISHED PRODUCT -
ADVECIT CAPSULE,	ADVECIT CAPSULE,		DELORBIS	Manufacture - Change to in-process
HARD	HARD		PHARMACEU	tests or limits applied during the manufacture of the finished product -
250MG	250MG	7645/23T	TICALS LTD	Other changes
				B.II.b.5.z B.II.b.5.z - QUALITY
ADVECIT	ADVECIT			CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process
CAPSULE,	CAPSULE,		DELORBIS	tests or limits applied during the
HARD	HARD	7040/007	PHARMACEU	manufacture of the finished product -
20MG	20MG	7649/23T	TICALS LTD	Other changes

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ADVECIT CAPSULE, HARD 5MG EFLUELDA	ADVECIT CAPSULE, HARD 5MG EFLUELDA	7650/23T	DELORBIS PHARMACEU TICALS 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 B.I.a.5.a B.I.a.5.a - QUALITY
SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 60MCG/DO SE	SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 60MCG/DO SE	6005/23T	SANOFI PASTEUR.	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
OLMESART AN TAD TABLET, FILM COATED 20MG	OLMESART AN 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)
OLMESART AN TAD TABLET, FILM COATED 10MG	OLMESART AN 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)
OLMESART AN TAD TABLET, FILM COATED 40MG	OLMESART AN 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)
FLUDARAB INE ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION AND INJECTION 25MG/ML	FLUDARAB INE ACCORD CONCENT RATE 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, CHEWABL E / DISPERSIB LE 50MG	LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 50MG	5207/23T, 5208/23T, 5209/23T	GLAXOSMITH KLINE (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, CHEWABL E / DISPERSIB LE 100MG	LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 100MG	5204/23T, 5205/23T, 5206/23T	GLAXOSMITH KLINE (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
				the active substance - Minor changes to an approved test procedure
				B.I.b.2.a B.I.b.2.a - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
LAMICTAL	LAMICTAL			Control of active substance - Change in
TABLET,	TABLET,			test procedure for active substance or
CHEWABL	CHEWABL		GLAXOSMITH	starting material/reagent/intermediate
E/		5040/00T 5044/00T	KLINE	used in the manufacturing process of
DISPERSIB		5210/23T, 5211/23T,	(IRELAND)	the active substance - Minor changes to
LE 25MG	LE 25MG	5212/23T	LIMITED	an approved test procedure B.I.b.2.a B.I.b.2.a - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
LAMICTAL	LAMICTAL			Control of active substance - Change in
TABLET,	TABLET,			test procedure for active substance or
CHEWABL	CHEWABL		GLAXOSMITH	starting material/reagent/intermediate
Ε/	Ε/		KLINE	used in the manufacturing process of
DISPERSIB	DISPERSIB	5216/23T, 5217/23T,	(IRELAND)	the active substance - Minor changes to
LE 2MG	LE 2MG	5218/23T	LIMITED	an approved test procedure
				B.I.b.2.a B.I.b.2.a - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
				Control of active substance - Change in
TABLET,	TABLET,			test procedure for active substance or
CHEWABL E /	CHEWABL E /		GLAXOSMITH KLINE	starting material/reagent/intermediate used in the manufacturing process of
		5213/23T, 5214/23T,	(IRELAND)	the active substance - Minor changes to
LE 5MG	LE 5MG	5215/23T		an approved test procedure
	00			B.I.b.2.a B.I.b.2.a - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
LAMICTAL	LAMICTAL			Control of active substance - Change in
TABLET,	TABLET,			test procedure for active substance or
CHEWABL	CHEWABL		GLAXOSMITH	starting material/reagent/intermediate
Ε/	E /		KLINE	used in the manufacturing process of
DISPERSIB	DISPERSIB	5201/23T, 5202/23T,	(IRELAND)	the active substance - Minor changes to
LE 200MG	LE 200MG	5203/23T	LIMITED	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
ADVECIT	ADVECIT			the dossier to comply with the
CAPSULE,	CAPSULE,		DELORBIS	provisions of an updated general
HARD	HARD		PHARMACEU	monograph of the Ph. Eur for the
250MG	250MG	7623/23T	TICALS LTD	finished product*
				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
ADVECIT	ADVECIT			the dossier to comply with the
CAPSULE,	CAPSULE,		DELORBIS	provisions of an updated general
HARD	HARD		PHARMACEU	monograph of the Ph. Eur for the
180MG	180MG	7624/23T	TICALS LTD	finished product*
				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
ADVECIT	ADVECIT			limits of the finished product - Update of the dossier to comply with the
CAPSULE,	CAPSULE,		DELORBIS	provisions of an updated general
HARD	HARD		PHARMACEU	monograph of the Ph. Eur for the
140MG	140MG	7625/23T	TICALS LTD	finished product*
				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
ADVECIT CAPSULE,	ADVECIT CAPSULE,		DELORBIS	the dossier to comply with the
HARD	HARD		PHARMACEU	provisions of an updated general monograph of the Ph. Eur for the
100MG	100MG	7626/23T	TICALS LTD	finished product*
10000	10000			

				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
ADVECIT	ADVECIT			limits of the finished product - Update of the dossier to comply with the
CAPSULE,	CAPSULE,		DELORBIS	provisions of an updated general
HARD 20MG	HARD 20MG	7627/23T	PHARMACEU TICALS LTD	monograph of the Ph. Eur for the finished product*
201010	201010	1021/201	HOALG LID	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
ADVECIT	ADVECIT		DELORBIS	provisions of an updated general
CAPSULE, HARD 5MG	CAPSULE, HARD 5MG	7628/23T	PHARMACEU TICALS LTD	monograph of the Ph. Eur for the finished product*
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of human medicinal products intended to implement the outcome of a
				procedure concerning PSUR or PASS,
CREDANIL	CREDANIL			or the outcome of the assessment done by the competent authority under
TABLET	TABLET			Articles 45 or 46 of Regulation
100MG/25M G	100MG/25M G	7394/23T	REMEDICA LTD	1901/2006 - Implementation of wording agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products intended to implement the outcome of a
				procedure concerning PSUR or PASS,
CREDANIL	CREDANIL			or the outcome of the assessment done by the competent authority under
TABLET	TABLET		DEMERICA	Articles 45 or 46 of Regulation
100MG/10M G	100MG/10M G	7395/23T	REMEDICA LTD	1901/2006 - Implementation of wording agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of human medicinal products intended to implement the outcome of a
				procedure concerning PSUR or PASS,
CREDANIL	CREDANIL			or the outcome of the assessment done by the competent authority under
TABLET	TABLET			Articles 45 or 46 of Regulation
250MG/25M G	250MG/25M G	7393/23T	REMEDICA LTD	1901/2006 - Implementation of wording agreed by the competent authority
SODIUM	SODIUM			
CHLORIDE/ DEMO	CHLORIDE/ DEMO			
SOLUTION FOR	SOLUTION FOR			
INTRAVEN	INTRAVEN		THE STAR	
OUS INFUSION	OUS INFUSION		MEDICINES IMPORTERS	A.z A.z - ADMINISTRATIVE
0.9% W/V	0.9% W/V	6260/23T	CO. LTD	CHANGES - Other variation

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MONTOL TABLET, CHEWABL E 5MG	MONTOL TABLET, CHEWABL E 5MG	7606/23T	DELORBIS PHARMACEU TICALS 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 C.I.2.z C.I.2.z - SAFETY, EFFICACY,
MONTOL TABLET, CHEWABL E 4MG	MONTOL TABLET, CHEWABL E 4MG	7607/23T	DELORBIS PHARMACEU TICALS LTD	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary 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 PHARMACEU TICALS 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, DISPERSIB LE 20MG	FELDENE TABLET, DISPERSIB LE 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
BOCOUTU RE POWDER FOR SOLUTION FOR INJECTION 50U	BOCOUTU RE POWDER FOR SOLUTION FOR INJECTION 50U	6758/23T	MERZ PHARMACEU TICALS 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
BOCOUTU RE POWDER FOR SOLUTION FOR INJECTION 1000	BOCOUTU RE POWDER FOR SOLUTION FOR INJECTION 100U	6757/23T	MERZ PHARMACEU TICALS 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
TARGINAC T TABLET, PROLONG ED- RELEASE 10/5MG	TARGINAC T TABLET, PROLONG ED- RELEASE 10/5MG	1725/23T, 1726/23T	MUNDIPHARM A PHARMACEU TICALS 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

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				by the competent authority under Articles 45 or 46 of Regulation
				1901/2006 - Implementation of wording
				agreed by the competent authority that require additional minor assessment,
				e.g. translations are not yet agreed
				upon C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS, or the outcome of the assessment done
				by the competent authority under
TARGINAC T TABLET.	TARGINAC T TABLET,			Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
PROLONG	PROLONG		MUNDIPHARM	agreed by the competent authority that
ED- RELEASE	ED- RELEASE		A PHARMACEU	require additional minor assessment,
5/2.5MG	5/2.5MG	1719/23T, 1720/23T	TICALS LTD	e.g. translations are not yet agreed upon
				C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a procedure concerning PSUR or PASS,
				or the outcome of the assessment done
TARGINAC	TARGINAC			by the competent authority under Articles 45 or 46 of Regulation
T TABLET,	T TABLET,			1901/2006 - Implementation of wording
PROLONG ED-	PROLONG ED-		MUNDIPHARM A	agreed by the competent authority that require additional minor assessment,
RELEASE	RELEASE		PHARMACEU	e.g. translations are not yet agreed
40/20MG	40/20MG	1721/23T, 1722/23T	TICALS LTD	upon C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS, or the outcome of the assessment done
				by the competent authority under
TARGINAC T TABLET,	TARGINAC T TABLET,			Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
PROLONG	PROLONG		MUNDIPHARM	agreed by the competent authority that
ED- RELEASE	ED- RELEASE		A PHARMACEU	require additional minor assessment, e.g. translations are not yet agreed
20/10MG	20/10MG	1723/23T, 1724/23T	TICALS LTD	upon
				B.II.h.1.b.1 B.II.h.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT -
OCTANINE	OCTANINE			Adventitious Agents Safety - Update to
POWDER AND	POWDER AND			the "Adventitious Agents Safety Evaluation" information (section 3.2.A.2)
SOLVENT	SOLVENT			- Replacement of obsolete studies
FOR SOLUTION	FOR SOLUTION			related to manufacturing steps and adventitious agents already reported in
FOR	FOR			the dossier - with modification of risk
INJECTION 500IU/VIAL	INJECTION 500IU/VIAL		OCTAPHARM	assessment B.I.a.2.c B.I.a.2.c - QUALITY
(100IU/ML)	(100IU/ML)	5880/23T, 5881/23T	A (IP) SPRL	CHANGES - ACTIVE SUBSTANCE -

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				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.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
OCTANINE	OCTANINE			CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the
POWDER	POWDER			manufacturing process of the active
AND	AND			substance - The change refers to a
SOLVENT	SOLVENT			biological / immunological substance or
FOR	FOR			use of a different chemically derived
SOLUTION	SOLUTION			substance in the manufacture of a
FOR	FOR			biological/immunological substance,
INJECTION 1000IU/VIA	INJECTION 1000IU/VIA			which may have a significant impact on the quality, safety and efficacy of the
L(100IU/ML	L(100IU/ML		OCTAPHARM	medicinal product and is not related to a
))	5878/23T, 5879/23T	A (IP) SPRL	protocol
_/	/			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
ARCHIFAR	ARCHIFAR			the manufacturing process of the active
POWDER	POWDER			substance or change in the manufacturer (including where relevant
FOR	FOR			quality control testing sites) of the active
SOLUTION	SOLUTION			substance, where no Ph. Eur. Certificate
FOR	FOR			of Suitability is part of the approved
INJECTION	INJECTION			dossier - Introduction of a manufacturer
/INFUSION	/INFUSION		MEDOCHEMIE	of the active substance supported by an
500MG	500MG	7172/23T	LTD	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
ARCHIFAR	ARCHIFAR			substance or change in the
POWDER	POWDER			manufacturer (including where relevant
FOR	FOR			quality control testing sites) of the active
SOLUTION FOR	SOLUTION			substance, where no Ph. Eur. Certificate
INJECTION	FOR INJECTION			of Suitability is part of the approved dossier - Introduction of a manufacturer
/INFUSION	/INFUSION		MEDOCHEMIE	of the active substance supported by an
1G	1G	7171/23T	LTD	ASMF
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
SOLPADEI NE	SOLPADEI NE			of Ph. Eur. certificate of suitability: For
SOLUBLE	SOLUBLE		OMEGA PHARMA	an active substance For a starting material/reagent/intermediate used in
TABLET	TABLET	7736/23T	HELLAS S.A	the manufacturing process of the active
				and manufacturing process of the doll'e

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				substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
ABIRATER ONE/SAND OZ TABLET, FILM COATED	ABIRATER ONE/SAND OZ TABLET, FILM COATED		SANDOZ PHARMACEU	B.II.b).1. a) Secondary packaging site variation Type IAIN (B.II.b.1.a): to add Logifarma S.r.I, Via Campobello 1, 00071 Pomezia, Italy as an alternative site responsible for secondary
500MG	500MG	6990/23T	TICALS D.D.	packaging of the finished product.
BORTEZO MIB/TEVA POWDER FOR SOLUTION FOR INJECTION 3.5MG/VIAL	BORTEZO MIB/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/75M G	CURILEN CAPSULE, HARD 10MG/75M G	6490/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES SA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
CURILEN CAPSULE, HARD 5MG/100M G	CURILEN CAPSULE, HARD 5MG/100M G	6491/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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 PHARMACEU TICAL LABORATORI ES 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	PHARMATHE N 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	PHARMATHE N 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

OCTAGAM OCTAGAM B.III.1.a.2 B.III.1.a.2 - QUALITY OCTAGAM OCTAGAM B.III.1.a.2 B.III.1.a.2 SOLUTION FOR FOR FOR INFUSION INFUSION TO35/23T OCTAPHARM A (IP) SPRL B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA Substance For a tarting material/reagent/intermediate used the manufacturing process of the ad SOLUTION SOLUTION FOR INFUSION INFUSION OCTAPHARM JOMG/ML 7035/23T A (IP) SPRL B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA Soluction Soluction Soluction GOCTAGAM COTAGAM Soluction Solution Solution FOR INFUSION Solution To35/23T CHANGES - CEP/TSE/MONOGRA Submission of a new or updated F Soution of a new or updated F Eur. Certificate of suitability or delet	bility - PHS h. ion for in ctive ean
OCTAGAM OCTAGAM SOLUTION SOLUTION FOR FOR INFUSION INFUSION SOMG/ML 7035/23T A (IP) SPRL B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F Eur. Certificate of suitability or deler of Ph. Eur. certificate of suitability: F an active substance For a starting material/reagent/intermediate used the manufacturing process of the ad substance For an excipient - Europ Pharmacopoeial Certificate of Suitation CCTAPHARM Updated certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA	PHS h. ion or in ctive ean
OCTAGAM OCTAGAM SOLUTION OCTAGAM SOLUTION SOLUTION FOR INFUSION INFUSION INFUSION 50MG/ML 7035/23T A (IP) SPRL B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F Eur. Certificate of suitability or deleted of Ph. Eur. certificate of suitability: F an active substance For a starting material/reagent/intermediate used the manufacturing process of the addition solution substance For an excipient - Europ Pharmacopoeial Certificate of Suitation other relevant Ph. Eur. Monograph Updated certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA Submission of a new or updated F Submission of a new or updated F	rh. ion For in ctive ∋an
OCTAGAM OCTAGAM OCTAGAM OCTAGAM SOLUTION SOLUTION FOR FOR INFUSION INFUSION 50MG/ML 7035/23T A (IP) SPRL B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA Corract Solution COCTAGAM OCTAGAM Solution Solution FOR FOR INFUSION INFUSION Solution COCTAPHARM Solution Solution Solution<	rh. ion For in ctive ∋an
OCTAGAM OCTAGAM OCTAGAM OCTAGAM SOLUTION SOLUTION FOR FOR INFUSION INFUSION 50MG/ML 7035/23T A (IP) SPRL B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F	ion For in ctive ean
OCTAGAM OCTAGAM OCTAGAM OCTAGAM SOLUTION SOLUTION FOR FOR INFUSION INFUSION 50MG/ML 7035/23T A (IP) SPRL B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F	For in ctive ean
OCTAGAM OCTAGAM SOLUTION SOLUTION FOR FOR INFUSION INFUSION 50MG/ML 7035/23T A (IP) SPRL B.III.1.a.2 B.III.1.a.2 QUALITY CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F	in tive ean
OCTAGAM SOLUTION FOR OCTAGAM SOLUTION FOR OCTAGAM SOLUTION FOR automatic INFUSION 50MG/ML INFUSION 50MG/ML OCTAPHARM 7035/23T OCTAPHARM A (IP) SPRL the manufacturing process of the automatic substance For an excipient - Europ Pharmacopoeial Certificate of Suita to the relevant Ph. Eur. Monograph Updated certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 QUALITY CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F	tive ean
OCTAGAM OCTAGAM SOLUTION SOLUTION FOR FOR INFUSION INFUSION 50MG/ML 7035/23T A (IP) SPRL B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F	ean
FOR INFUSION 50MG/ML FOR INFUSION 50MG/ML FOR INFUSION 7035/23T OCTAPHARM A (IP) SPRL to the relevant Ph. Eur. Monograph Updated certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F	bility
INFUSION INFUSION OCTAPHARM Updated certificate from an already approved manufacturer 50MG/ML 7035/23T A (IP) SPRL Updated certificate from an already approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F	
B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F	
CHANGES - CEP/TSE/MONOGRA - Submission of a new or updated F	
EUR CERTIFICATE OF SUITADUITY OF DEP	
of Ph. Eur. certificate of suitability: I	
an active substance For a starting material/reagent/intermediate used	in
the manufacturing process of the ad	tive
OCTAGAM OCTAGAM substance For an excipient - Europ SOLUTION SOLUTION Pharmacopoeial Certificate of Suita	
FOR FOR to the relevant Ph. Eur. Monograph	-
INFUSIONINFUSIONOCTAPHARMUpdated certificate from an already10%10%7036/23TA (IP) SPRLapproved manufacturer	
C.I.3.z C.I.3.z - SAFETY, EFFICAC	
PHARMACOVIGILANCE CHANGE HUMAN AND VETERINARY	S -
MEDICINAL PRODUCTS - Change	(s)
in the Summary of Product Characteristics, Labelling or Packag	
Leaflet of human medicinal product	5
intended to implement the outcome procedure concerning PSUR or PA	
or the outcome of the assessment of	
YASMINEL YASMINEL by the competent authority under LE LE Articles 45 or 46 of Regulation	
TABLET, TABLET, 1901/2006 - Implementation of work	
FILM FILM agreed by the competent authority is require additional minor assessment	
0.02MG/3M 0.02MG/3M BAYER e.g. translations are not yet agreed	-,
G G 1441/23T HELLAS ABEE upon C.I.2.a C.I.2.a - SAFETY, EFFICAC	Y.
PHARMACOVIGILANCE CHANGE	
HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change	(s)
in the Summary of Product	. ,
EFAVIREN EFAVIREN Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimila	
Z Z medicinal products following	
AUROBIND AUROBIND assessment of the same change fo O TABLET, O TABLET, AUROBINDO reference product - Implementation	
FILM FILM PHARMA change(s) for which no new addition	nal
COATEDCOATED(MALTA)data is required to be submitted by600MG600MG6324/23TLIMITEDMAH	ne
AMOXAPE AMOXAPE B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT	-
N N Control of finished product - Chang	e in
CAPSULE, HARDCAPSULE, HARDthe specification parameters and/or limits of the finished product - Other	
250MG 250MG 7604/23T LTD changes	
AMOXAPE AMOXAPE B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT	-
CAPSULE, CAPSULE, 7603/23T LTD Control of finished product - Chang	

				the encolfication records and the
HARD 500MG	HARD 500MG			the specification parameters and/or limits of the finished product - Other changes
METOCLO PRAMIDE ACCORD TABLET 10MG	METOCLO PRAMIDE 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
METOCLO PRAMIDE ACCORD TABLET 10MG	METOCLO PRAMIDE 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 OROMUCO SAL SPRAY 0.2%	HEXALEN OROMUCO SAL 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
PARACETA MOL ACCORD SOLUTION FOR INFUSION 10MG/ML	PARACETA MOL 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
ROSUVAD OR TABLET, FILM COATED 5MG	ROSUVAD OR 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)

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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) B.III.1.a.2 B.III.1.a.2 - QUALITY
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.	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.1.2.a C.1.2.a - SAFETY, EFFICACY,
STATOL TABLET, FILM COATED 20MG	STATOL TABLET, FILM COATED 20MG	7079/23T	DELORBIS PHARMACEU TICALS LTD	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

			l	1
STATOL TABLET, FILM COATED 10MG	STATOL TABLET, FILM COATED 10MG	7080/23T	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 5MG	STATOL TABLET, FILM COATED 5MG	7081/23T	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 40MG	STATOL TABLET, FILM COATED 40MG	7078/23T	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
HEXALEN OROMUCO SAL SOLUTION 5MG/5ML	HEXALEN OROMUCO SAL 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
ABIRATER ONE SAPIENS TABLET, FILM COATED 500MG	ABIRATER ONE SAPIENS TABLET, FILM COATED 500MG	7271/23T, 7272/23T, 7273/23T, 7274/23T	SAPIENS PHARMACEU TICALS 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

	T	1	1	
				not have a significant effect on the overall quality of the active substance
				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
AMLODIPIN	AMLODIPIN			limits of the immediate packaging of the finished product - Addition of a new
ACCORD	ACCORD		ACCORD	specification parameter to the
TABLET 10MG	TABLET 10MG	6201/22T 6202/22T	HEALTHCARE S.L.U	specification with its corresponding test method
TOIMG	TUNG	6201/23T, 6202/23T	3.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
AMLODIPIN ACCORD	AMLODIPIN ACCORD		ACCORD	finished product - Addition of a new specification parameter to the
TABLET	TABLET		HEALTHCARE	specification with its corresponding test
5MG	5MG	6203/23T, 6204/23T	S.L.U	method B.II.a.1.a B.II.a.1.a - QUALITY
SRIVASSO	SRIVASSO			CHANGES - FINISHED PRODUCT -
INHALATIO N	INHALATIO N			Description and composition - Change or addition of imprints, bossing or other
POWDER,	POWDER,		BOEHRINGER	markings including replacement, or
HARD CAPSULE	HARD CAPSULE		INGELHEIM INTERNATION	addition of inks used for product marking - Changes in imprints, bossing
18MCG	18MCG	6741/23T	AL GMBH	or other markings
				A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name and/or address of a
				manufacturer/importer of the finished
				product (including batch release or quality control testing sites) - The
				activities for which the
				manufacturer/importer is responsible do
				not include batch release
				- Change in the name and/or address
	1			of: a manufacturer (including where
1				
				relevant quality control testing sites); or an ASMF holder; or a supplier of the
MERONEM	MERONEM			relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material,
POWDER	POWDER			relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the
POWDER FOR SOLUTION	POWDER FOR SOLUTION			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
POWDER FOR SOLUTION FOR	POWDER FOR SOLUTION FOR			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
POWDER FOR SOLUTION	POWDER FOR SOLUTION			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
POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA	POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA	0000/00T_0007/00T	PFIZER	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
POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA L	6986/23T, 6987/23T	PFIZER HELLAS AE	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)
POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA	POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG/VIA	6986/23T, 6987/23T 1935/23T, 1936/23T, 1937/23T		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

FOR ORAL	FOR ORAL		(IRELAND)	Eur. Certificate of suitability or deletion
SUSPENSI	SUSPENSI			of Ph. Eur. certificate of suitability: For
ON	ON			an active substance For a starting
250MG/5ML	250MG/5ML			material/reagent/intermediate used in
				the manufacturing process of 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
			<u> </u>	C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s) in the Summary of product
OMPRANY	OMPRANY			Characteristics, Labelling or Package
T GASTRO-	T GASTRO-			Leaflet intended to implement the
RESISTAN	RESISTAN			outcome of a PRAC signal
			DIAL	recommendation: implementation of
CAPSULE, HARD	CAPSULE, HARD		BIAL- PORTELA &	wording agreed by the competent authority that do not require any further
20MG	20MG	7616/23T	CA, SA	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
				C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s) in the SmPC, labelling or package
LOSARTAN	LOSARTAN			leaflet of human medicinal products in
/HYDROCH	/HYDROCH			order to adapt to a recommendation of a
LOROTHIA	LOROTHIA			competent authority , e.g. a Core
ZIDE KRKA TABLET,	ZIDE KRKA TABLET,			SmPC, following the assessment of an Urgent Safety Restriction etc.
FILM	FILM			Implementation of wording agreed by
COATED	COATED			the competent authority that require
100MG/25M	100MG/25M	0470/00T 0470/00T	KRKA D.D.	additional minor assessment, e.g.
G	G	6178/23T, 6179/23T	NOVO MESTO	translations are not yet agreed upon. C.I.2.a C.I.2.a - SAFETY, EFFICACY,
LOSARTAN	LOSARTAN			PHARMACOVIGILANCE CHANGES -
/HYDROCH	/HYDROCH			HUMAN AND VETERINARY
LOROTHIA				MEDICINAL PRODUCTS - Change(s)
ZIDE KRKA TABLET,	ZIDE KRKA TABLET,			in the Summary of Product Characteristics, Labelling or Package
FILM	FILM		KRKA D.D.	Leaflet of a generic/hybrid/biosimilar
COATED	COATED	6180/23T, 6181/23T	NOVO MESTO	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.
				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 -
ULTRAVIST	ULTRAVIST			HUMAN AND VETERINARY
370 SOLUTION	370 SOLUTION			MEDICINAL PRODUCTS - Change(s) in the Summary of Product
FOR	FOR			Characteristics, Labelling or Package
INJECTION	INJECTION		BAYER	Leaflet due to new quality, preclinical,
76.9%	76.9%	140/23T	HELLAS ABEE	clinical or pharmacovigilance data C.I.11.b C.I.11.b - SAFETY,
				EFFICACY, PHARMACOVIGILANCE
				CHANGES - HUMAN AND
				VETERINARY MEDICINAL PRODUCTS - Introduction of, or
				change(s) to, the obligations and
				conditions of a marketing authorisation,
				including the risk management plan - Implementation of change(s) which
				require to be further substantiated by
				new additional data to be submitted by
				the MAH where significant assessment by the competent authority is required*
				C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
ULTRAVIST 300	ULTRAVIST 300			HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
SOLUTION	SOLUTION			in the Summary of Product
FOR	FOR		DAVED	Characteristics, Labelling or Package
INJECTION 62.34%	INJECTION 62.34%	141/23T	BAYER HELLAS ABEE	Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
				B.III.2.b B.III.2.b - QUALITY CHANGES
WATER FOR	WATER FOR			- CEP/TSE/MONOGRAPHS - Change
INJECTION	INJECTION			to comply with Ph. Eur. or with a national pharmacopoeia of a Member
SOLVENT	SOLVENT			State - Change to comply with an
FOR	FOR			update of the relevant monograph of the
PARENTER AL USE	PARENTER AL USE			Ph. Eur. or national pharmacopoeia of a Member State
100% W/V	100% W/V	6726/23T, 6727/23T	DEMO S.A.	B.II.d.2.d B.II.d.2.d - QUALITY

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				CHANGES - FINISHED PRODUCT -
				Control of finished product - Change in test procedure for the finished product -
				Other changes to a test procedure
				(including replacement or addition)
				B.I.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
		0000 /00T 0000 /00T		CHANGES - ACTIVE SUBSTANCE -
		6238/23T, 6239/23T,		Control of active substance - Change in
		6240/23T, 6241/23T, 6242/23T, 6243/23T,		test procedure for active substance or star
		6244/23T, 6245/23T,		B.I.a.1.b B.I.a.1.b - QUALITY
		6246/23T, 6247/23T,		CHANGES - ACTIVE SUBSTANCE -
ADVANTAN	ADVANTAN	6248/23T, 6249/23T,		Manufacture - Change in the
CREAM	CREAM	6250/23T, 6251/23T,	LEO PHARMA	manufacturer of a starting
0.1% (W/W)	0.1% (W/W)	6252/23T	A/S	material/reagent/intermediat
				B.II.b.3.a B.II.b.3.a - QUALITY
				CHANGES - FINISHED PRODUCT -
	LACOSADE			Manufacture - Change in the
LACOSADE	L TABLET,			manufacturing process of the finished product, including an intermediate used
FILM	FILM		DELORBIS	in the manufacture of the finished
COATED	COATED		PHARMACEU	product - Minor change in the
200MG	200MG	7575/23T	TICALS LTD	manufacturing process
				B.II.b.3.a B.II.b.3.a - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change in the
LACOSADE L TABLET,	LACOSADE L TABLET,			manufacturing process of the finished
FILM	FILM		DELORBIS	product, including an intermediate used in the manufacture of the finished
COATED	COATED		PHARMACEU	product - Minor change in the
150MG	150MG	7576/23T	TICALS LTD	manufacturing process
				B.II.b.3.a B.II.b.3.a - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change in the
LACOSADE	LACOSADE			manufacturing process of the finished
L TABLET, FILM	L TABLET, FILM			product, including an intermediate used in the manufacture of the finished
COATED			DELORBIS PHARMACEU	product - Minor change in the
100MG	100MG	7577/23T	TICALS LTD	manufacturing process
				B.II.b.3.a B.II.b.3.a - QUALITY
LACOSADE	LACOSADE			CHANGES - FINISHED PRODUCT -
L TABLET,	L TABLET,			Manufacture - Change in the
FILM	FILM		DELORBIS	manufacturing process of the finished
COATED	COATED	7570/00T	PHARMACEU	product, including an intermediate used
50MG	50MG	7578/23T	TICALS LTD	in the manufacture of the finished

				product - Minor change in the
DENTOCAI NE SOLUTION FOR INJECTION 40MG/0.01 MG/ML	DENTOCAI NE SOLUTION FOR INJECTION 40MG/0.01 MG/ML	6857/23T	INIBSA DENTAL S.L.U.	manufacturing process B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DENTOCAI NE SOLUTION FOR INJECTION 40MG/0.005 MG/ML	DENTOCAI NE 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/1 00G	LIOTON 1000 GEL 100000IU/1 00G	7187/22T, 367/23T	A. MENARINI INDUSTRIE FARMACEUTI CHE 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 PHARMACEU TICALS 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 PARENTER AL USE 100% W/V	WATER FOR INJECTION SOLVENT FOR PARENTER AL USE 100% W/V	6587/23T	THE STAR MEDICINES IMPORTERS CO. LTD	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
ZOVIDUO CREAM (50MG/10M G)/G	ZOVIDUO CREAM (50MG/10M G)/G	3722/23T	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ ΑΕ) GLAXOSMITH	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.a A.5.a - ADMINISTRATIVE
OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	OTRIVIN ADVANCE NASAL SPRAY, SOLUTION	3721/23T	ΚLIΝΕ ΚΑΤΑΝΑΛΩΤΙ ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ	CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The

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			ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ	activities for which the
			(GSK CH	manufacturer/importer is responsible include batch release
			ΕΛΛΑΣ ΑΕ)	
SALOFALK SUPPOSIT ORY 1G	SALOFALK SUPPOSIT ORY 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
VINCRISTI NE SULPHATE SOLUTION FOR INJECTION OR INFUSION 1MG/ML	VINCRISTI NE 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	OCTAPHARM A (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
CASPOFU NGIN DEMO POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 50MG/VIAL	CASPOFU NGIN DEMO POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 50MG/VIAL	6828/22T	DEMO S.A.	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
CASPOFU NGIN DEMO POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 70MG/VIAL PAROXETI	CASPOFU NGIN DEMO POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 70MG/VIAL PAROXETI	6827/22T	DEMO S.A.	B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation C.I.2.a C.I.2.a - SAFETY, EFFICACY,
NE AUROBIND O TABLET, FILM	NE AUROBIND O TABLET, FILM	3285/23T	AUROBINDO PHARMA (MALTA) LIMITED	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product

COATED	COATED			Characteristics, Labelling or Package
20MG	20MG			Leaflet of a generic/hybrid/biosimilar
				medicinal products following
				assessment of the 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.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
PAROXETI	PAROXETI			Leaflet of a generic/hybrid/biosimilar
NE	NE			medicinal products following
AUROBIND	AUROBIND			assessment of the same change for the
O TABLET,	O TABLET,		AUROBINDO	reference product - Implementation of
FILM	FILM		PHARMA	change(s) for which no new additional
COATED	COATED		(MALTA)	data is required to be submitted by the
30MG	30MG	3284/23T	LIMITED	MAH
301010	301013	3204/231		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
BRUFEDOL	BRUFEDOL			used in the manufacturing process of
TABLET,	TABLET,			the active substance - Other changes to
FILM	FILM		VIATRIS	a test procedure (including replacement
COATED	COATED		HEALTHCARE	or addition) for the active substance or a
600MG	600MG	6598/23T	LIMITED.	starting material/intermediate
0001010	0001010	0000/201	EIMITED.	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
BRUFEDOL	BRUFEDOL			used in the manufacturing process of
TABLET,	TABLET,			the active substance - Other changes to
FILM	FILM		VIATRIS	a test procedure (including replacement
COATED	COATED		HEALTHCARE	or addition) for the active substance or a
400MG	400MG	6599/23T	LIMITED.	starting material/intermediate
				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,
OCTAGAM	OCTAGAM			PHARMACOVIGILANCE CHANGES -
SOLUTION	SOLUTION			HUMAN AND VETERINARY
FOR	FOR			MEDICINAL PRODUCTS -
INFUSION	INFUSION		OCTAPHARM	Implementation of an agreed wording,
50MG/ML	50MG/ML	5073/23T, 5074/23T	A (IP) SPRL	no new data submitted
FLUNOL	FLUNOL			A.1 A.1 - ADMINISTRATIVE
CAPSULE,	CAPSULE,			CHANGES - Change in the name
HARD	HARD	7400/00T	PHARMA Q	and/or address of the marketing
100MG	100MG	7496/23T	AE	authorisation holder
				C.I.3.z C.I.3.z - SAFETY, EFFICACY,
VENLAFAXI	VENLAFAXI			PHARMACOVIGILANCE CHANGES -
N TAD	N TAD			HUMAN AND VETERINARY
CAPSULE,	CAPSULE,			MEDICINAL PRODUCTS - Change(s)
HARD,	HARD,			in the Summary of Product
PROLONG	PROLONG			Characteristics, Labelling or Package
ED-	ED-			Leaflet of human medicinal products
RELEASE	RELEASE		TAD PHARMA	intended to implement the outcome of a
150MG	150MG	3576/23T, 3577/23T	GMBH	procedure concerning PSUR or PASS,
UNIO	TUNIU	0010/201, 0011/201		procedure concerning r SUR OF FASS,

				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
VENLAFAXI N TAD CAPSULE, HARD, PROLONG ED- RELEASE 75MG	VENLAFAXI N TAD CAPSULE, HARD, PROLONG ED- 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
MIDAZOLA M B. BRAUN SOLUTION FOR INJECTION OR INFUSION 5MG/ML	MIDAZOLA M 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
MIDAZOLA M B. BRAUN SOLUTION FOR INJECTION OR INFUSION 1MG/ML	MIDAZOLA M 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
				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
EREZEL TABLET	EREZEL TABLET			place, or supplier of a starting material, reagent or excipient (when mentioned in
10MG	10MG	7419/21T, 7420/21T	VENIFAR LTD	the dossier)*
				C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
FLAGYL TABLET	FLAGYL TABLET		SANOFI WINTHROP	MEDICINAL PRODUCTS - Implementation of an agreed wording,
400MG	400MG	358/23T	INDUSTRIE.	no new data submitted
				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
CERTICAN	CERTICAN		NOVARTIS	update of the relevant monograph of the
TABLET 1MG	TABLET 1MG	5522/23T, 5523/23T, 5524/23T	IRELAND LIMITED	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.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
CERTICAN	CERTICAN		NOVARTIS	State - Change to comply with an update of the relevant monograph of the
TABLET 0.5MG	TABLET 0.5MG	5516/23T, 5517/23T, 5518/23T	IRELAND LIMITED	Ph. Eur. or national pharmacopoeia of a Member State
0.5101G	0.5101G	5510/251		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
CERTICAN TABLET	CERTICAN TABLET	5513/23T, 5514/23T,	NOVARTIS IRELAND	starting material/reagent/intermediate used in the manufacturing process of
0.75MG	0.75MG	5515/23T	LIMITED	the active substance - Minor changes to

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				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	5490/23T	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/850M G	MAYMETSI TABLET, FILM COATED 50MG/850M G	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
SANDOSTA TIN LAR POWDER AND SOLVENT	SANDOSTA TIN 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 FOR devices (when	
	mentioned in the dossier) t or addition of a supplier
ON FOR ON FOR	
INJECTION INJECTION 20MG 20MG	
SANDOSTA SANDOSTA	
POWDER POWDER	
	e.7.b - QUALITY
	INISHED PRODUCT - ure system - Change in
	kaging components or
	mentioned in the dossier)
30MG 30MG 6383/23T LIMITED - Replacement SANDOSTA SANDOSTA	t or addition of a supplier
TIN LAR TIN LAR	
POWDER POWDER AND AND	
	e.7.b - QUALITY
	INISHED PRODUCT -
	ure system - Change in kaging components or
INJECTION INJECTION IRELAND devices (when	mentioned in the dossier)
	t or addition of a supplier
	I - SAFETY, EFFICACY, IGILANCE CHANGES -
HUMAN AND	VETERINARY
MEDICINAL P in the Summar	RODUCTS - Change(s)
	s, Labelling or Package
	an medicinal products
	plement the outcome of a cerning PSUR or PASS,
FYLEPSIA FYLEPSIA or the outcome	e of the assessment done
	ent authority under 46 of Regulation
COATED COATED PHARMACEU 1901/2006 - In	nplementation of wording
	competent authority - SAFETY, EFFICACY,
	IGILANCE CHANGES -
HUMAN AND	VETERINARY
MEDICINAL P in the Summar	RODUCTS - Change(s)
	s, Labelling or Package
	an medicinal products
	plement the outcome of a cerning PSUR or PASS,
FYLEPSIA FYLEPSIA or the outcome	e of the assessment done
	ent authority under 46 of Regulation
COATED COATED PHARMACEU 1901/2006 - In	nplementation of wording
2MG 2MG 5684/23T TICAL CO INC agreed by the	competent authority
	- SAFETY, EFFICACY, IGILANCE CHANGES -
HUMAN AND	VETERINARY
MEDICINAL P in the Summar	RODUCTS - Change(s)
	s, Labelling or Package
Leaflet of hum	an medicinal products
	plement the outcome of a cerning PSUR or PASS,
FYLEPSIA FYLEPSIA or the outcome	e of the assessment done
	ent authority under 46 of Regulation
	nplementation of wording
6MG 6MG 5682/23T TICAL CO INC agreed by the	competent authority
FYLEPSIA FYLEPSIA ELPEN C.I.3.a C.I.3.a	- SAFETY, EFFICACY,
	IGILANCE CHANGES -

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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 PHARMACEU TICAL 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.3.a C.I.3.a - SAFETY, EFFICACY,
FYLEPSIA TABLET, FILM COATED 12MG	FYLEPSIA TABLET, FILM COATED 12MG	5679/23T	ELPEN PHARMACEU TICAL CO INC	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
ROSUVAST ATIN ACCORD TABLET, FILM COATED 5MG	ROSUVAST ATIN 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
ROSUVAST ATIN ACCORD TABLET, FILM COATED 10MG	ROSUVAST ATIN 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
ROSUVAST ATIN ACCORD TABLET, FILM	ROSUVAST ATIN 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

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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
				C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package
ROSUVAST ATIN ACCORD	ROSUVAST ATIN ACCORD			Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the
TABLET, FILM	TABLET, FILM		ACCORD	reference product - Implementation of change(s) for which no new additional
COATED 40MG	COATED 40MG	4495/23T	HEALTHCARE S.L.U	data is required to be submitted by the MAH
MAYMETSI TABLET,	MAYMETSI TABLET,			B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or
FILM	FILM			storage conditions of the finished product - Extension of the shelf life of
50MG/1000 MG	50MG/1000 MG	3853/23T	TAD PHARMA GMBH	the finished product - As packaged for sale (supported by real time data)
MAYMETSI TABLET,	MAYMETSI TABLET,			B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or
FILM COATED	FILM COATED			storage conditions of the finished product - Extension of the shelf life of
50MG/850M G	50MG/850M G	3852/23T	TAD PHARMA GMBH	the finished product - As packaged for sale (supported by real time data)
				C.I.4 C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
			ASPEN	MEDICINAL PRODUCTS - Change(s) in the Summary of Product
TRACRIUM INJECTION 10MG/ML	TRACRIUM INJECTION 10MG/ML	3824/23T	PHARMA TRADING LIMITED	Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
TOWG/WL	TOWG/WE	5024/201		C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
ESOMEPR AZOLE KRKA	ESOMEPR AZOLE KRKA			in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
GASTRO- RESISTAN	GASTRO- RESISTAN			medicinal products following assessment of the same change for the
T CAPSULE, HARD	T CAPSULE, HARD		KRKA D.D.	reference product - Implementation of change(s) for which no new additional data is required to be submitted by the
40MG	40MG	733/23T	NOVO MESTO	MAH C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
ESOMEPR AZOLE	ESOMEPR AZOLE			MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package
KRKA GASTRO-	KRKA GASTRO-			Leaflet of a generic/hybrid/biosimilar medicinal products following
RESISTAN T CAPSULE,	RESISTAN T CAPSULE,			assessment of the same change for the reference product - Implementation of change(s) for which no new additional
HARD 20MG	HARD 20MG	734/23T	KRKA D.D. NOVO MESTO	data is required to be submitted by the MAH

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VILDAGLIP TIN ACCORD TABLET 50MG	VILDAGLIP TIN 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
SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI ON FOR INJECTION 20MG	SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI ON 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)
SANDOSTA TIN SOLUTION FOR INJECTION & INFUSION 0.1MG/ML	SANDOSTA TIN 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)
SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI ON FOR INJECTION 10MG	SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI ON 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)
SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI ON FOR INJECTION 30MG	SANDOSTA TIN LAR POWDER AND SOLVENT FOR SUSPENSI ON 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)

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VINORELBI NE	VINORELBI NE			A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
ACCORD	ACCORD			and/or address of a
CONCENT	CONCENT			manufacturer/importer of the finished
RATE FOR SOLUTION	RATE FOR SOLUTION			product (including batch release or quality control testing sites) - The
FOR	FOR		ACCORD	activities for which the
INFUSION	INFUSION		HEALTHCARE	manufacturer/importer is responsible do
10MG/ML	10MG/ML	6389/23T	S.L.U	not 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
				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
CERTICAN	CERTICAN		NOVARTIS	dossier; or a manufacturer of a novel
TABLET	TABLET	6969/23T, 6970/23T,	IRELAND	excipient (where specified in the
1MG	1MG	6971/23T	LIMITED	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 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
CERTICAN	CERTICAN		NOVARTIS	dossier; or a manufacturer of a novel
TABLET 0.5MG	TABLET 0.5MG	6963/23T, 6964/23T, 6965/23T	IRELAND LIMITED	excipient (where specified in the technical dossier)
0.31010	0.31010	0300/201		A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
				and/or address of a
				manufacturer/importer of the 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
	CERTICAN		NOVARTIS	of: a manufacturer (including where
CERTICAN TABLET	TABLET	6960/23T, 6961/23T,	IRELAND	relevant quality control testing sites); or an ASMF holder; or a supplier of the
0.75MG	0.75MG	6962/23T	LIMITED	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 A.4 A.4 - ADMINISTRATIVE CHANGES Change in the name and/or address
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 A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address
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 A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address
A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the 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
and/or address of a manufacturer/importer of the 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
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
manufacturer/importer is responsible do not include batch release A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address
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
CERTICAN CERTICAN NOVARTIS Outside approved TABLET TABLET 6966/23T, 6967/23T, IRELAND excipient (where specified in the
0.25MG 0.25MG 6968/23T LIMITED technical dossier) C.I.2.a C.I.2.a - SAFETY, EFFICACY,
PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
MEDICINAL PRODUCTS - Change(s) in the Summary of Product
ATAZANAV ATAZANAV ATAZANAV ATAZANAV ATAZANAV ATAZANAV ATAZANAV
IR IR assessment of the same change for the reference product - Implementation of
CAPSULE, HARDCAPSULE, HARDACCORD HEALTHCAREchange(s) for which no new additional data is required to be submitted by the
150MG 150MG 4473/23T S.L.U MAH C.I.2.a C.I.2.a - SAFETY, EFFICACY,
PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package
ATAZANAV ATAZANAV ATAZANAV ATAZANAV
IR IR assessment of the same change for the reference product - Implementation of
CAPSULE, HARD CAPSULE, HARD ACCORD change(s) for which no new additional data is required to be submitted by the
300MG 300MG 4472/23T S.L.U MAH B.II.d.1.z B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT -
Changes - Finished product - Change in the specification parameters and/or
MONOCLO MONOCLO Imits of the finished product - Change in the specification parameters and/or
X POWDER X POWDER FOR FOR accurately describe the appearance of
SOLUTIONSOLUTIONthe drug productFORFOR1480/23T, 1481/23T,B.II.d.2.d B.II.d.2.d - QUALITYINJECTIONINJECTION1482/23T, 1483/23T,CHANGES - FINISHED PRODUCT -
INSECTIONINSECTION146/231, 1463/231,CHANGES - FINISHED PRODUCT -/INFUSION/INFUSION1484/231, 1485/231,MEDOCHEMIEControl of finished product - Change in250MG250MG1486/23TLTDtest procedure for the finished product -

MONOCLO X POWDER FOR SOLUTION FOR SOUMG MONOCLO X POWDER FOR SOUMG MONOCLO X POWDER FOR SOUMG <th></th> <th></th> <th>1</th> <th></th> <th></th>			1		
MONOCLO X POWDER FOR MONOCLO SOLUTION FOR MONOCLO X POWDER SOLUTION MEDOCHEMIE X POWDER SOLUTION MEDOCHE					(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
INJECTION /INFUSIONINJECTION /INFUSION1475/23T, 1476/23T, 1477/23T, 1478/23T,MEDOCHEMIE LTDof a new specification parameter to the specification with its corresponding tes method500MG500MG1479/23TLTDB.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 - Change in the specification parameters and/or limits of the 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 - Change in the specification parameters and/or limits of the finished product - Change in test procedure for the 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 - Tightening of specification limits B.II.d.1.c B.II.d.1.c B.II.d.1.c QUALITY	X POWI FOR SOLUTI	DER X POWDER FOR ON SOLUTION	1473/23T 1474/23T		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 - Tightening of specification limits B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of 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
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	MONOC X POW FOR SOLUTI FOR INJECT /INFUSI	CLO MONOCLO DER X POWDER FOR ON SOLUTION FOR ION INJECTION ON /INFUSION	1466/23T, 1467/23T, 1468/23T, 1469/23T, 1470/23T, 1471/23T,	MEDOCHEMIE	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 - Tightening of specification limits B.II.d.1.c B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product -

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INFUSION /INFUSION Heb0CHEMIE closure (immediate packaging) - Sterile 250MG 250MG 148923T LTD medicinal products MONOCLO MONOCLO XPOWDER BII.e.4.c - QUALITY FOR FOR FOR BII.e.4.c - QUALITY FOR FOR FOR Container dosure system - Ohange in FOR FOR FOR MEDOCHEMIE Container dosure system - Ohange in INJECTION INJECTION MEDOCHEMIE Container dosure system - Ohange in MONOCLO MONOCLO MONOCLO NONOCLO NONOCLO YPOWDER FOR FOR FOR FOR FOR FOR FOR FOR FOR FOR SOLUTION INFUSION INECTION MEDOCHEMIE BII.e.4.c B.II.e.4.c - OLIALITY FOR FOR FOR FOR FOR FOR SOLUTION INFUSION INFUSION C.I.2.a C.I.2.a - SAETY, EFFICACY, PHANDACE CHANCES - HUMAN AND VETERINARY MEDICINAL PRODUCTS GENEMEN TTABLET, FILM C.I.2.a C.I.2.a - SAETY, EFFICACY, PHARMACEU GENEMEN TABLET, TABLET, FILM C.I.2.a C.I.2.a - SAETY, EFFICACY, PHARMACEU C.I.2.a C.I.2.a - SAETY, EFFICACY, PHARMACEU GENEMEN GENEMEN TABLET, FILM<	-				
250MG 250MG 1489/23T LTD medicinal products 0.5 MONOCLO NONOCLO NONONCLO NONOCLO NON				MEDOCHEMIE	
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5MG5MG442/21TTICALS LTDMAHA.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 variationCOLMIFEN TABLET 10MG7406/23T, 7407/23T, 7408/23TREMEDICA LTDMEDICINAL PRODUCTS - Other variationDAPTOMY CINDAPTOMY CINNORIDEM ENTERPRISEB.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT -					
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COLMIFEN TABLETCOLMIFEN 7406/23T, 7407/23T,REMEDICA LTDactive substance or of an excipient 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 variationDAPTOMY CINDAPTOMY CINNORIDEM ENTERPRISEB.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT -					
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COLMIFEN TABLETCOLMIFEN 7406/23T, 7407/23T,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 variationDAPTOMY CINDAPTOMY CINNORIDEM ENTERPRISEB.II.f.1.b.1 B.II.f.1.b.1 - QUALITY ENTERPRISE					
COLMIFEN TABLETCOLMIFEN 7406/23T, 7407/23T,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 variationDAPTOMY CINDAPTOMY CINNORIDEM ENTERPRISEB.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT -					
COLMIFEN TABLETCOLMIFEN TABLETin 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 variationDAPTOMY CINDAPTOMY CINNORIDEM ENTERPRISEB.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT -					
COLMIFEN TABLETCOLMIFEN 7406/23T, 7407/23T, 10MGFinished product - Other changes C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variationDAPTOMY CINDAPTOMY CINNORIDEM ENTERPRISEB.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT -					
COLMIFEN TABLETCOLMIFEN TABLETPHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation10MG10MG7406/23T, 7407/23T, 7408/23TREMEDICA LTDMEDICINAL PRODUCTS - Other variationDAPTOMYDAPTOMY CINDAPTOMY CINNORIDEM ENTERPRISEB.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT -					finished product - Other changes
COLMIFEN TABLETCOLMIFEN TABLETHUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation10MG10MG7408/23TLTDMEDICINAL PRODUCTS - Other variationDAPTOMY CINDAPTOMY CINCINNORIDEM ENTERPRISEB.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT -					
TABLETTABLET7406/23T, 7407/23T, 7408/23TREMEDICA LTDMEDICINAL PRODUCTS - Other variation10MG10MG7408/23TLTDvariationDAPTOMYDAPTOMYNORIDEMB.II.f.1.b.1 B.II.f.1.b.1 - QUALITY ENTERPRISEB.II.f.1.b.1 B.II.f.1.b.1 - QUALITY					
10MG 10MG 7408/23T LTD variation DAPTOMY DAPTOMY NORIDEM B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CIN CIN ENTERPRISE CHANGES - FINISHED PRODUCT -			7406/00T 7407/00T		
DAPTOMY DAPTOMY NORIDEM B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY CIN CIN ENTERPRISE CHANGES - FINISHED PRODUCT -				-	
CIN CIN ENTERPRISE CHANGES - FINISHED PRODUCT -			1+00/201		
				-	
	-	-	5802/23T		Stability - Change in the shelf-life or

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POWDER FOR	POWDER FOR			storage conditions of the finished product - Extension of the shelf life of
SOLUTION	SOLUTION			the finished product - As packaged for
FOR	FOR			sale (supported by real time data)
INJECTION	INJECTION			
/INFUSION 500MG/VIA	/INFUSION 500MG/VIA			
L	L			
DAPTOMY	DAPTOMY			
NORIDEM POWDER	NORIDEM POWDER			
FOR	FOR			B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
SOLUTION	SOLUTION			CHANGES - FINISHED PRODUCT -
FOR INJECTION	FOR INJECTION			Stability - Change in the shelf-life or storage conditions of the finished
/INFUSION	/INFUSION		NORIDEM	product - Extension of the shelf life of
350MG/VIA	350MG/VIA		ENTERPRISE	the finished product - As packaged for
L	L	5803/23T	S LTD	sale (supported by real time data)
				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 -
OCTAGAM	OCTAGAM			Manufacture - Changes in the manufacturing process of the active
SOLUTION	SOLUTION			substance - The change refers to a
FOR	FOR			biological / immunological substance or
INFUSION 10%	INFUSION 10%	2469/23T, 2470/23T, 2471/23T, 2472/23T		use of a different chemically derived substance in
10 /0	1070	2471/23T, 2472/23T	A (IP) SPRL	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
TACROLIM	TACROLIM			CHANGES - FINISHED PRODUCT -
US	US			Container closure system - Change in
ACCORD	ACCORD		ACCORD	shape or dimensions of the container or
OINTMENT 0.1%	OINTMENT 0.1%	7146/23T, 7147/23T	HEALTHCARE S.L.U	closure (immediate packaging) - Non- sterile medicinal products
0.170	0.170	1110/201, 1171/201	0.1.0	B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
	DEXETA			- Submission of a new or updated Ph.
DEXETA EYE	EYE			Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
DROPS,	DROPS,			an active substance For a starting
SOLUTION	SOLUTION	0055/00T		material/reagent/intermediate used in
1.5MG/ML	1.5MG/ML	6255/23T	SIFI S.P.A	the manufacturing process of the active

				substance For an excipient - European Pharmacopoeial Certificate of Suitability
				to the relevant Ph. Eur. Monograph - Updated certificate from an already
SIMEVIN TABLET, FILM COATED 50MG/850M G	SIMEVIN TABLET, FILM COATED 50MG/850M G	6184/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES SA	approved manufacturer B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
SIMEVIN TABLET, FILM COATED 50MG/1000 MG	SIMEVIN TABLET, FILM COATED 50MG/1000 MG	6185/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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
SOLIFENA CIN SANDOZ TABLET, FILM COATED 5MG	SOLIFENA CIN 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
SOLIFENA CIN SANDOZ TABLET, FILM COATED 10MG	SOLIFENA CIN 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
DULOXETI NE ACCORD GASTRO- RESISTAN T CAPSULE, HARD 30MG	DULOXETI NE ACCORD GASTRO- RESISTAN T 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
DULOXETI NE ACCORD GASTRO- RESISTAN T CAPSULE, HARD 60MG	DULOXETI NE ACCORD GASTRO- RESISTAN T 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

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				to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
DULOXETI NE ACCORD GASTRO- RESISTAN T CAPSULE, HARD 30MG	DULOXETI NE ACCORD GASTRO- RESISTAN T 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 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)*
DULOXETI NE ACCORD GASTRO- RESISTAN T CAPSULE, HARD 60MG	DULOXETI NE ACCORD GASTRO- RESISTAN T 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)*
DULOXETI NE ACCORD GASTRO- RESISTAN T CAPSULE, HARD 30MG	DULOXETI NE ACCORD GASTRO- RESISTAN T 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
DULOXETI NE ACCORD GASTRO- RESISTAN T CAPSULE,	DULOXETI NE ACCORD GASTRO- RESISTAN T 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

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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
DULOXETI NE ACCORD GASTRO- RESISTAN T	DULOXETI NE ACCORD GASTRO- RESISTAN T			
CAPSULE, HARD 30MG	CAPSULE, HARD 30MG	7930/20T	ACCORD HEALTHCARE S.L.U	C.I z) Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products Other variation
DULOXETI NE ACCORD GASTRO- RESISTAN T	DULOXETI NE ACCORD GASTRO- RESISTAN T			
CAPSULE, HARD 60MG	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/75M G	CURILEN CAPSULE, HARD 10MG/75M G	6394/23T, 6395/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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/100M G	CURILEN CAPSULE, HARD 5MG/100M G	6398/23T, 6399/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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/100M	CURILEN CAPSULE, HARD 10MG/100M		UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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
G	G	6396/23T, 6397/23T	ES SA	manufacturer
CURILEN CAPSULE, HARD 5MG/75MG	CURILEN CAPSULE, HARD 5MG/75MG	6392/23T, 6393/23T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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/75M G	CURILEN CAPSULE, HARD 10MG/75M G	6494/20T, 6495/20T, 6496/20T, 6497/20T, 6498/20T, 6499/20T, 6500/20T, 6501/20T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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

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CURILEN CAPSULE, HARD 5MG/100M G	CURILEN CAPSULE, HARD 5MG/100M G	6486/20T, 6487/20T, 6488/20T, 6489/20T, 6490/20T, 6491/20T, 6492/20T, 6493/20T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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/100M G	CURILEN CAPSULE, HARD 10MG/100M G	6478/20T, 6479/20T, 6480/20T, 6481/20T, 6482/20T, 6483/20T, 6484/20T, 6485/20T	UNI-PHARMA KLEON TSETIS PHARMACEU TICAL LABORATORI ES 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 PHARMACEU TICAL LABORATORI ES 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, 9675/22T, 9678/22T, 9679/22T, 9680/22T, 9681/22T, 9682/22T	REMEDICA	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 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 -
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				B.II.b.3.a B.II.b.3.a - QUALITY
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				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
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				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
		9683/22T, 9684/22T,		B.II.f.1.d B.II.f.1.d - QUALITY
		9685/22T, 9686/22T,		CHANGES - FINISHED PRODUCT -
		9687/22T, 9688/22T,		Stability - Change in the shelf-life or
AMLORINE	AMLORINE	9689/22T, 9690/22T,		B.II.d.1.z B.II.d.1.z - QUALITY
TABLET 5MG	TABLET 5MG	9691/22T, 9692/22T, 9693/22T	REMEDICA LTD	CHANGES - FINISHED PRODUCT -
SiviG	SIVIG	9093/221		Control of finished product - Change in C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
MIDAZOLA	MIDAZOLA			Characteristics, Labelling or Package Leaflet of human medicinal products
M ACCORD	M ACCORD			intended to implement the outcome of a
SOLUTION	SOLUTION			procedure concerning PSUR or PASS,
FOR	FOR			or the outcome of the assessment done
INJECTION				by the competent authority under
OR INFUSION	OR INFUSION		ACCORD HEALTHCARE	Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
1MG/ML	1MG/ML	6596/23T	S.L.U	agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
MIDAZOLA M ACCORD	MIDAZOLA M ACCORD			MEDICINAL PRODUCTS - Change(s) in the Summary of Product
SOLUTION	SOLUTION			Characteristics, Labelling or Package
FOR	FOR			Leaflet of human medicinal products
INJECTION	INJECTION			intended to implement the outcome of a
OR	OR		ACCORD	procedure concerning PSUR or PASS,
	INFUSION	6507/00T	HEALTHCARE	or the outcome of the assessment done
5MG/ML	5MG/ML	6597/23T	S.L.U	by the competent authority under

Image: Instant State State 1901/2006 - Implementation overlang Image: Implementation of working states AS a AS a - ADMINISTRATIVE Image: Im			1		Articles 45 or 40 of Degulation
LASIX LASIX <td< td=""><td></td><td></td><td></td><td></td><td>Articles 45 or 46 of Regulation</td></td<>					Articles 45 or 46 of Regulation
LASIX LASIX LASIX LASIX LASIX LASIX CHARGE - Change in the name and/or address of a manded ture/importer of the finished product (including batch release or quadred turber is responsible include batch release or quadred to particles, appoulde quadred turber is responsible include batch release or quadred to particles, quadred turber is responsible include to responsible include to responsible include to response of the finished product - Quadred turber is response of the finished product - Quadred turber is response of the finished product - Quadred turber is response of the quadred general or excliption or manufacturere is particles, quadred quadr					
LASIX LASIX LASIX SANOFI manufacturer/importer of the finished product (including batch release or quality control testing sites). The activities for which the machine discussion of the finished product include batch release or quality control testing sites). The activities for which the machine discussion of the finished product - Change in the number of units (e.g. Change unside the name of the currently approved pack sizes of the finished product - Change in the number of units (e.g. Change unside the number of units (e.g. Change unside the name of the currently approved pack sizes (for a change substance, intermediate or finished product, expansion (for the net one quality, proteincade, change to inporter, intermediate or finished product, expansion (for the net lakes place. Constend to include the desse; for a cache substance, intermediate or finished product, expansion (for the desse; for a cache substance, intermediate or finished product, expansion (for the desse; for a cache substance, intermediate or finished product, expansion (for the desse; for a cache substance, intermediate or finished product, expansion (for the desse; for a cache substance, intermediate or finished product, expansion (for the desse; for a cache substance, intermediate or finished product, expansion (for thesthered) approved pacend (for th					
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TABLET TABLET TABLET WINTHROP manufacturer/importer is responsible SeVOFLUR SEVOFLUR BILB.5.a.2 DULTY BILB.5.a.2 DULTY ANE- ANE- ANE- ANE- PIRAMAL NAPCUR, PIRAMAL Container closure system - change in the number of units (e.g., the second of the inside d product - Change in the number of units (e.g., the second of the conders, etc.) in a pack - Change outside the range of the conders d biels, ampounded pack sizes 100% V/V 3367/23T CARE B.V. CLAC Obange(b) in the Summary of Package Lastlet due to new quality, predinced, clinical or pharmacry glance data sizes 100% V/V 3367/23T CLAXOSMITH CLA Cobange(b) in the Summary of Package Lastlet due to new quality, predinced, clinical or pharmacry glance data sizes 200MG/SML 200MG/SML 7319/23T LIMITED. A 7 A 7 ADMINISTRATIVE 200MG/SML 200MG/SML 7319/23T LIMITED. A 7 A 7 aDMINISTRATIVE 200MG/SML 200MG/SML 7319/23T JOHNSON & Summary of neargenetistics, Labelling or exclusing material, reagent or exclus					
40MG 40MG 5158/21T INDUSTRIE. Include batch release """ SEVOFLUR ANE- ANE- PIRAMAL SEVOFLUR ANE- PIRAMAL BILe 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 on uside the range of the currently approved pack sizes 100% V/V 100% V/V 3367/23T CARE B.V. CARE B.V. Change on uside the range of the currently approved pack sizes 20VIRAX QCALX QCARC B.V. CARE B.V. C1.4 Change(s) in the Summary of Package Leafter due to new quality, preclinical, clinical or pharmacovigilance data. 200MG/SML 200MG/SML 7319/23T LIMITED. A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturing sites remainder of mished product, packaging site, manufacturing sites remainder for batch release, site where batch control taskes place, or supplier or a starting material; reagent or excipient (when menioned in the dossier)* 74BLET, TABLET, T	-				
SEVOFLUR ANE- PIRAMAL INHALATIO B.II.2.5.a.2 B.II.6.5.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. NAPOUR, LIQUID INHALATIO INHALATIO INHALATIO INHALATIO INWAVOUR, LIQUID PIRAMAL CRITICAL CONSUMERX PIRAMAL CRITICAL CRITICAL CARE B.V. CARE B.V. CARE B.V. CARE B.V. CORAL SUSPENSI ORAL SUSPENSI ON 200MG/5ML 200/IRAX 200MG/5ML 200/IRAX CORAL SUSPENSI ON 200MG/5ML 200MG/5ML 7319/23T VIDDUM 200MG/5ML 7319/23T CARE B.V. CLA Change(S) in the Summary of Product Characteristics, Labeling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. VIDDUM 200MG/5ML 7319/23T UINITED. A.7 A 7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance. Intermediate or insisted product, packaging site, manufacturing sites for a tarking material, reagent or excipient (when metioned in the dasaier)'' B.II.D.2 as II.D.2 a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change a transpendent and quality control testing of the finished product - Replacement or addition of a site where batch release arrangements and quality control testing of the finished product - Replacement or addition of S0MG/1000 SOM			5150/01T	-	
SEVOFLUR ANE- CHANGES - FINSHED PRODUCT - Container obsure system - Change in pack size of the finished product - Change in he number of units (e.g. that ALTO N VAPOUR, I UOUD CRITICAL Change on the number of units (e.g. that and the number	401VIG	40MG	5158/211	INDUSTRIE.	
ANE: ANE: Container closure system - Change in pack size of the finished product - Change in the number of units (e.g., tablets, angoules, etc.) in a pack - Change outside the range of the currently approved pack size of the finished product - Change in the number of units (e.g., tablets, angoules, etc.) in a pack - Change outside the range of the currently approved pack sizes 20VIRAX ZOVIRAX CARE B.V. CARE B.V. Change outside the range of the currently approved pack sizes 20VIRAX ZOVIRAX CARE B.V. C.1.4 Change(s) in the Summary of Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. 0RAL SUSPENSI TRADING SERVICES 200MG/GML 200MG/GML 7319/23T LIMITED. A.7.4.7 - ADMINISTRATIVE CHANGES - INISHED PRODUCT - Manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturing sites for a starting material, reagent or excipient (when mentioned in the dossier) B.IIb.2 a - INISHED PRODUCT - Manufacture - Change in graderial control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier) YEDFA TABLET, FLIM JOHNSON & JOHNSON & JOHNSON & JOHNSON & SB6/23T, 5397/23T AE VEDFA TABLET, FLIM SB6/23T, 5397/23T AE VEDFA TABLET, FLIM SB.11.2 B.11.2 - QUALITY CHANGES - FINISHED PRODUCT - Other	SEVOELUR	SEVOELUR			
PIRAMAL PIRAMAL pack size of the finished product - INHALATIO PIRAMAL Change in the number of units (e.g. tablets. ampoules, etc.) in a pack - LIQUID LIQUID CRITICAL Change in the number of units (e.g. tablets. ampoules, etc.) in a pack - 20VIRAX GRAL CARE B.V. Change on the number of units (e.g. tablets. ampoules, etc.) in a pack - 20VIRAX CARE B.V. CLAVCOSMIT CLA Change on tablets. ampoules, etc.) and participation of the summary of Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. 200MG/5ML 200MG/5ML 7319/23T LIMITED. A.7 A 7 - ADIMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product. metalena, clinical or pharmacovigilance data. 200MG/5ML 200MG/5ML 7319/23T LIMITED. A.7 A 7 - ADIMINISTRATIVE CHANGES - Deletion of manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting metrial, reagent or excipient (when metrial) reagent in the dossier)* B.IIb.2.a - QUALITY IMODIUM IMODIUM JUHNSON R JUHNSON R B.IIb.2.a - BIIb.2.a - QUALITY TABLET, T					
INHALATIO INHALATIO N VAPOUR, LIQUID PIRAMAL CRITICA					
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PLUS PLUS JOHNSON batch release arrangements and quality control testing of the finished product - 2MG/125M 2MG/125M 5396/23T, 5397/23T CONSUMER batch release arrangements and quality control testing of the finished product - VEDFA VEDFA VEDFA TABLET, TABLET, TABLET, FILM FILM FILM COATED COATED SOMG/1000 BMG 5855/22T N S.A. FINISHED PRODUCT - Other variation VEDFA VEDFA VEDFA TABLET, FILM FILM FILM FINISHED PRODUCT - Other variation VEDFA VEDFA VEDFA TABLET, FILM B.II.Z B.II.Z - QUALITY CHANGES - G G 5855/22T N S.A. FINISHED PRODUCT - Other variation VEDFA TABLET, FILM FILM B.II.Z B.II.Z - QUALITY CHANGES - G G 5856/22T N S.A. FINISHED PRODUCT - Other variation G G 5856/22T N S.A. B.II.d 2.d G.II.d 2.d - QUALITY CHANGES - G G 5856/22T N S.A. B.II.d 2.d G.II.d 2.d - QUALITY CHANGES - G G 5856/22T N S.A. B.II.d 2.d G.II.d 2.d - QUALITY CHANGES -					
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2MG/125M 2MG/125M CONSUMER Replacement or addition of a site where batch control/testing takes place VEDFA VEDFA TABLET, TABLET, TABLET, FILM FINISHED PRODUCT - Other variation G G 5856/22T N S.A. PHARMATHE B.II.Z B.II.Z - QUALITY CHANGES - FINISHED PRODUCT - Other variation G G 5856/22T N S.A. FINISHED PRODUCT - Other variation B.II.d.1.6.1.6.1.6.1.6.1.6.1.6.1.6.1.6.1.6.1					
G G 5396/23T, 5397/23T AE batch control/testing takes place VEDFA VEDFA VEDFA TABLET, FILM FILM COATED COATED COATED S0MG/1000 PHARMATHE B.II.z B.II.z - QUALITY CHANGES - FING MG 5855/22T N S.A. FINISHED PRODUCT - Other variation VEDFA VEDFA TABLET, FILM FILM COATED COATED 5855/22T N S.A. FINISHED PRODUCT - Other variation SOMG/850M SOMG/850M PHARMATHE B.II.z B.II.z - QUALITY CHANGES - FINISHED COATED S0MG/850M B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - G G 5856/22T N S.A. B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - G G 5856/22T N S.A. B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - G G 5856/22T N S.A. B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - G G 5856/22T N S.A. B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - G G S856/22T N S.A. B.II.d.1.h B.II.d.1.h B.II.d.1.h B.II.d.1.h B.II.d.1.h B.II.d.1.h B.II.d.1.h B.II.d.1.h B.II.d.1.h B.I					
VEDFA TABLET, FILM VEDFA TABLET, FILM VEDFA COATED TABLET, COATED FILM S0MG/1000 MG 5855/22T PHARMATHE B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation VEDFA VEDFA TABLET, FILM TABLET, FILM FILM FILM COATED S0MG/850M 50MG/850M PHARMATHE B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation G G 5856/22T PHARMATHE B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation G G 5856/22T N.S.A. B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation RIVAROXA RIVAROXA BAN/SAND RIVAROXA BAN/SAND RIVAROXA BAN/SAND RIVAROXA BAN/SAND S3900/23T, 3901/23T, 3900/23T, 3901/23T, 3900/23T, 3901/23T, SANDOZ monograph of the Ph. Eur for the finished product -			5396/23T. 5397/23T		
TABLET, FILMTABLET, FILMTABLET, FILMTABLET, FILMTABLET, FINSHED PRODUCT - Other variationVEDFA TABLET, FILMVEDFA TABLET, FILMVEDFA FILMB.II.Z B.II.Z - QUALITY CHANGES - FINISHED PRODUCT - Other variationVEDFA TABLET, FILM GVEDFA COATEDVEDFA SoMG/850MB.II.Z B.II.Z - QUALITY CHANGES - FINISHED PRODUCT - Other variationVEDFA TABLET, GG5856/22TPHARMATHE N S.A.B.II.Z B.II.Z - QUALITY CHANGES - FINISHED PRODUCT - Other variationB.II.Z B.II.Z - QUALITY CHANGES - COATEDG5856/22TPHARMATHE N S.A.B.II.Z B.II.Z - QUALITY CHANGES - FINISHED PRODUCT - Other variationB.II.Z B.II.Z - QUALITY CHANGES - COATEDG5856/22TPHARMATHE N S.A.B.II.Z B.II.Z - QUALITY CHANGES - CHANGES - FINISHED PRODUCT - Other variationB.II.Z B.II.Z - QUALITY CHANGES - COATEDG5856/22TPHARMATHE N S.A.B.II.Z B.II.Z - QUALITY CHANGES - CHANGES - FINISHED PRODUCT - Control of finished product - Other variationRIVAROXA BAN/SAND OZ TABLET, FILMRIVAROXA BAN/SAND OZ OZ TABLET, FILMRIVAROXA BAN/SAND OZ OZ TABLET, FILM3900/23T, 3901/23T, 3900/23T, 3901/23T, SANDOZ PHARMACEUFIND PHARMACEU					
COATED 50MG/1000COATED 50MG/1000PHARMATHE N S.A.B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationVEDFA TABLET, FILM COATEDVEDFA TABLET, FILMN S.A.B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationS0MG/850M GCOATED S0MG/850M GS0MG/850M GPHARMATHE N S.A.B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationS0MG/850M GS0MG/850M GS856/22TPHARMATHE N S.A.B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Other variationS0MG/850M GGS856/22TN S.A.B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Other variationS0MG/850M GGS856/22TN S.A.B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other variation)RIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA COATEDRIVAROXA BAN/SANDS900/23T, 3901/23T, 3902/23T, 3901/23T,SANDOZ PHARMACEUmonograph of the Ph. Eur for the finished product*					
50MG/1000 MG50MG/1000 MGPHARMATHE N S.A.B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationVEDFA TABLET, FILM COATED S0MG/850M GVEDFA TABLET, FILMABLET, FILMB.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationS0MG/850M GS0MG/850M GPHARMATHE N S.A.B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationBS0MG/850M GS856/22TPHARMATHE N S.A.B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationBBS856/22TN S.A.B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.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 finished product*RIVAROXA BAN/SAND OZ TABLET, FILM COATEDRIVAROXA, 3900/23T, 3901/23T, 3902/23T, 3903/23T,SANDOZ PHARMACEU		FILM			
MGMG5855/22TN S.A.FINISHED PRODUCT - Other variationVEDFAVEDFATABLET,TABLET,FILMFILMCOATEDCOATED50MG/850MGGGG5856/22TPHARMATHEB.II.z B.II.z - QUALITY CHANGES -FINISHED PRODUCT - Other variationB.II.d.2.d B.II.d.2.d - QUALITYCHANGES - FINISHED PRODUCT - Other variationG5856/22TPHARMATHEB.II.d.2.d B.II.d.2.d - QUALITYCHANGES - FINISHED PRODUCT - Other variationControl 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 test procedure for the finished product - Change in test procedure for the 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*RIVAROXA BAN/SAND OZ3902/23T, 3901/23T, 3903/23T,FILM COATEDCOATEDSANDOZ PHARMACEUfinished product*	COATED	COATED			
VEDFA VEDFA TABLET, TABLET, FILM FILM COATED COATED 50MG/850M 50MG/850M G G 50MG/850M 5856/22T N S.A. FINISHED PRODUCT - Other variation B.II.d.2.d B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Other variation B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Other variation B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Other variation B.II.d.1.h B.II.d.2.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 variation) B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Update of VAROXA BAN/SAND OZ OZ TABLET, TABLET, FILM 3900/23T, 3901/23T, SANDOZ provisions of an updated general monograph of the Ph. Eur for the finished product*					
TABLET, FILM COATEDTABLET, FILM COATEDTABLET, FILM COATEDPHARMATHE N S.A.B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationGG5856/22TN S.A.B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Other variationGG5856/22TN S.A.B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Other variationGG5856/22TN S.A.B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other changes to a test procedure (including replacement or addition) B.I.I.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Other changes to a test procedure (including replacement or addition) B.I.I.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*		-	5855/22T	N S.A.	FINISHED PRODUCT - Other variation
FILM COATED 50MG/850M GFILM COATED 50MG/850M GFILM 5856/22TPHARMATHE N S.A.B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationBG5856/22TN S.A.B.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Other variationBBB.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*					
COATED 50MG/850M GCOATED 50MG/850M GPHARMATHE N S.A.B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationB.II.d.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Other variationB.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 - Other change in 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*					
50MG/850M G50MG/850M G5856/22TPHARMATHE N S.A.B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variationB.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 - 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*					
GG5856/22TN S.A.FINISHED PRODUCT - Other variationB.II.d.2.d B.II.d.2.d - QUALITYB.II.d.2.d - QUALITYCHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)RIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA FILMRIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA COATEDRIVAROXA 3900/23T, 3901/23T, 3903/23T,SANDOZ PHARMACEUFILM COATEDFILM 3902/23T, 3903/23T,SANDOZ PHARMACEU					
B.II.d.2.d B.II.d.2.d - QUALITYCHANGES - 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 - 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*			5856/22T		
RIVAROXA BAN/SAND OZ TABLET, FILMRIVAROXA FILMRIVAROXA 3900/23T, 3901/23T, 3903/23T, 3903/23T,CHANGES - FINISHED PRODUCT - Control of 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*		Ŭ			
RIVAROXA BAN/SAND OZ TABLET, FILMRIVAROXA FILMRIVAROXA 3900/23T, 3901/23T, 3903/23T, 3903/23T,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*					
RIVAROXA BAN/SAND OZ TABLET, FILMRIVAROXA FILMRIVAROXA 3900/23T, 3901/23T, 3903/23T, 3903/23T,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*					
RIVAROXA BAN/SAND OZ TABLET, FILMRIVAROXA BAN/SAND OZ TABLET, FILMRIVAROXA BAN/23T, 3901/23T, 3902/23T, 3903/23T,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*					
RIVAROXA BAN/SAND OZ TABLET, FILMRIVAROXA B300/23T, 3901/23T, 3902/23T, 3903/23T,(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*					Other changes to a test procedure
RIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA BAN/SANDRIVAROXA BAN/SANDCHANGES - 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 3902/23T, 3903/23T,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*					
RIVAROXA BAN/SANDRIVAROXA BAN/SANDControl 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 3902/23T, 3903/23T,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*					
RIVAROXA BAN/SAND OZRIVAROXA BAN/SAND OZthe 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*RIVAROXA BAN/SAND OZBAN/SAND OZthe 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*					
BAN/SANDBAN/SANDlimits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for theOZOZSANDOZTABLET,FILMFILMFILMCOATEDCOATEDSourceSourceFILMSourceFI					
OZOZthe dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*OZTABLET,TABLET,FILMFILM3900/23T, 3901/23T,COATEDCOATED3902/23T, 3903/23T,	-	-			
TABLET,TABLET,provisions of an updated generalFILMFILM3900/23T, 3901/23T,SANDOZmonograph of the Ph. Eur for theCOATEDCOATED3902/23T, 3903/23T,PHARMACEUfinished product*					
FILMFILM3900/23T, 3901/23T,SANDOZmonograph of the Ph. Eur for theCOATEDCOATED3902/23T, 3903/23T,PHARMACEUfinished product*	-	-			
COATED COATED 3902/23T, 3903/23T, PHARMACEU finished product*			3900/23T, 3901/23T	SANDOZ	
	20MG	20MG	3904/23T	TICALS D.D.	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
RIVAROXA BAN/SAND OZ TABLET, FILM COATED 15MG	RIVAROXA BAN/SAND OZ TABLET, FILM COATED 15MG	3905/23T, 3906/23T, 3907/23T, 3908/23T, 3909/23T	SANDOZ PHARMACEU TICALS 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 - Control of finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Minor changes to an approved test procedure
RIVAROXA BAN/SAND OZ TABLET, FILM COATED 10MG	RIVAROXA BAN/SAND OZ TABLET, FILM COATED 10MG	3910/23T, 3911/23T, 3912/23T, 3913/23T, 3914/23T	SANDOZ PHARMACEU TICALS 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 - Control of finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Tightening of specification limits B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Minor changes to an approved test procedure
SOOLANTR A CREAM 10MG/G	SOOLANTR A CREAM 10MG/G	6700/23T, 6701/23T	GALDERMA INTERNATION AL,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 -

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AREMED TABLET, FILM COATED 1MG	AREMED TABLET, FILM COATED 1MG	7398/23T	REMEDICA	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 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 /

				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 -
SYNTOCIL POWDER FOR SOLUTION FOR	SYNTOCIL POWDER FOR SOLUTION FOR	7476/23T, 7477/23T, 7478/23T, 7479/23T,		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
INJECTION /INFUSION 250MG	INJECTION /INFUSION 250MG	7480/23T, 7481/23T, 7482/23T, 7483/23T, 7484/23T	CODAL SYNTO LTD	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)

4004TABLET,TFILMFCOATED0400MG2ZILISTEN2POWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMATTETACCORD/TABLET,TFILMFCOATED025MG2TOPIRAMATTETACCORD/ACCORD/ACCORD/	PEROFEN 400 TABLET, FILM COATED			in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
4002TABLET,1FILMFCOATED0400MG2ZILISTEN2POWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMA1TE1ACCORD/TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD/ACCORD/ACCORD/	400 TABLET, FILM			medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
4002TABLET,1FILMFCOATED0400MG2ZILISTEN2POWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMA1TE1ACCORD/TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD/ACCORD/ACCORD/	400 TABLET, FILM			assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
4002TABLET,1FILMFCOATED0400MG2ZILISTEN2POWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMA1TE1ACCORD/TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD/ACCORD/ACCORD/	400 TABLET, FILM			reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
4002TABLET,1FILMFCOATED0400MG2ZILISTEN2POWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMA1TE1ACCORD/TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD/ACCORD/ACCORD/	400 TABLET, FILM			change(s) for which no new additional data is required to be submitted by the MAH
4002TABLET,1FILMFCOATED0400MG2ZILISTEN2POWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMA1TE1ACCORD/TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD/ACCORD/ACCORD/	400 TABLET, FILM			МАН
4002TABLET,1FILMFCOATED0400MG2ZILISTEN2POWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMA1TE1ACCORD/TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD/ACCORD/ACCORD/	400 TABLET, FILM			
4002TABLET,1FILMFCOATED0400MG2ZILISTEN2POWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMA1TE1ACCORD/TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD/ACCORD/ACCORD/	400 TABLET, FILM			B.II.d.1.c B.II.d.1.c - QUALITY
4002TABLET,1FILMFCOATED0400MG2ZILISTEN2POWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMA1TE1ACCORD/TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD/ACCORD/ACCORD/	400 TABLET, FILM			CHANGES - FINISHED PRODUCT -
TABLET,TFILMFCOATEDG400MGZZILISTENZPOWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMATTETACCORD/TABLET,TFILMFCOATEDG25MGZTOPIRAMATTETACCORD/ACCORD/ACCORD/ACCORD/	TABLET, FILM			Control of finished product - Change in the specification parameters and/or
FILMFCOATEDC400MGZZILISTENZPOWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMATTE1ACCORD/TABLET,1FILMFCOATEDC25MG2TOPIRAMATTE1ACCORD/ACCORD/ACCORD/	FILM			limits of the finished product - Addition
400MG2ZILISTEN2POWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMA1TE1ACCORD/TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD/ACCORD/ACCORD/ACCORD/	COATED			of a new specification parameter to the
ZILISTENZPOWDERFFORFSOLUTIONSFORFINJECTIONI/INFUSION/750MG7TOPIRAMATTETACCORDATABLET,TFILMFCOATEDC25MGZTOPIRAMATTETACCORDAACCORDA	400MG	7383/23T, 7384/23T	REMEDICA LTD	specification with its corresponding test method
FOR F SOLUTION S FOR F INJECTION I /INFUSION / 750MG 7 TOPIRAMA T ACCORD / TABLET, T FILM F COATED C 25MG 2 TOPIRAMA T TE T ACCORD /	ZILISTEN	7303/231, 7304/231	LID	method
SOLUTION S FOR F INJECTION I /INFUSION // 750MG 7 TOPIRAMA T TE 1 ACCORD // TABLET, 1 FILM F COATED 0 25MG 2 TOPIRAMA T TE 1 ACCORD //	POWDER			
FOR FINJECTION I INJECTION I /INFUSION / 750MG 7 TOPIRAMA T TE 1 ACCORD / TABLET, 1 FILM F COATED 0 25MG 2 TOPIRAMA T TE 1 ACCORD /	FOR SOLUTION			
/INFUSION/750MG7TOPIRAMA1TE1ACCORD/TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD/	FOR			
750MG7TOPIRAMA1TE1ACCORD4TABLET,1FILMFCOATED025MG2TOPIRAMA1TE1ACCORD4	INJECTION		NORIDEM	B.II.b.4.z B.II.b.4.z - QUALITY
TOPIRAMA TE T ACCORD A TABLET, T FILM F COATED C 25MG 2 TOPIRAMA TE T ACCORD A	/INFUSION 750MG	6955/23T	ENTERPRISE S LTD	CHANGES - FINISHED PRODUCT - Other variation
TE ACCORD A TABLET, T FILM F COATED C 25MG 2 TOPIRAMA T TE ACCORD A	TOPIRAMA	0000/201	5110	B.II.f.1.a.1 B.II.f.1.a.1 - QUALITY
TABLET,TFILMFCOATEDC25MG2TOPIRAMATTETACCORDA	TE			CHANGES - FINISHED PRODUCT -
FILMFCOATEDC25MG2TOPIRAMA1TE1ACCORDA				Stability - Change in the shelf-life or
COATED C 25MG 2 TOPIRAMA T TE 1 ACCORD 4	TABLET, FILM		ACCORD	storage conditions of the finished product - Reduction of the shelf life of
TOPIRAMA TE ACCORD	COATED		HEALTHCARE	the finished product - As packaged for
TE ACCORD A	25MG	6130/23T	S.L.U	
ACCORD A	TOPIRAMA TE			B.II.f.1.a.1 B.II.f.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT -
TABLET.	ACCORD			Stability - Change in the shelf-life or
	TABLET,			storage conditions of the finished
	FILM COATED		ACCORD HEALTHCARE	product - Reduction of the shelf life of the finished product - As packaged for
50MG 5	50MG	6129/23T	S.L.U	sale
	TOPIRAMA TE			B.II.f.1.a.1 B.II.f.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT -
	ACCORD			Stability - Change in the shelf-life or
TABLET,	TABLET,			storage conditions of the finished
	FILM		ACCORD HEALTHCARE	product - Reduction of the shelf life of the finished product - As packaged for
	COATED 200MG	6127/23T	S.L.U	the finished product - As packaged for sale
TOPIRAMA	TOPIRAMA		-	B.II.f.1.a.1 B.II.f.1.a.1 - QUALITY
	TE ACCORD			CHANGES - FINISHED PRODUCT -
	TABLET,			Stability - Change in the shelf-life or storage conditions of the finished
FILM F	FILM		ACCORD	product - Reduction of the shelf life of
	COATED	6109/00T	HEALTHCARE	the finished product - As packaged for
100MG 1	100MG	6128/23T	S.L.U	sale 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
	ACTILYSE POWDER			an B.II.e.2.c B.II.e.2.c - QUALITY
AND A	AND			CHANGES - FINISHED PRODUCT -
	SOLVENT	3470/23T, 3471/23T, 3472/23T, 3473/23T		Container closure system - Change in th
-	SOLUTION	3472/231, 3473/231, 3474/23T, 3475/23T,	BOEHRINGER	CHANGES - FINISHED PRODUCT -
FOR F			DOLININGER	
	FOR	3476/23T, 3477/23T,	INGELHEIM	Container closure system - Change in th
1MG/ML 1				
AND A SOLVENT S FOR F SOLUTION S FOR F INFUSION/I I	AND SOLVENT FOR	3472/23T, 3473/23T,	BOEHDINGED	CHANGES - FINISHED PRODUCT - Container closure system - Change in th B.II.e.2.b B.II.e.2.b - QUALITY

TUTECVI TUTECVI TUTECVI TUTECVI TUTECVI TUTECVI TUTECVI TUTECVI TUTECVI COMORES FINISHED PRODUCT - Mandacture - Change to In-process test B.IIb.33.B.IIb.33.A - QUALITY CHANGES - FINISHED PRODUCT - Mandacture - Change in the mandacture or the finished product - Minor change to an approved test procedure G 6058/23T, 6058/23T VIATRIS G 6058/23T, 6058/23T VIATRIS TUTECVI COMRE FILM - COMRE 6058/23T, 6058/23T TUTECVI COMRE FILM - COMPI CHANGES - FINISHED PRODUCT - Control of finished product - Minor changes to an approved test procedure TABLET, FILM COARED FILM - COMRE FILM - COMR					1
Container closure system - Change in Su B.I.B.J.S.D - OUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the product - Manufacture - Change in the manufacture - Change in the mane and/or address of the marketing authorisation holder TUTECVI COATED COATED CoATED S903/23T CVATES FUANGES - Change in the mane and/or address of the marketing authorisation holder					B.II.e.7.z B.II.e.7.z - QUALITY
Su BLIb.5b B.IIb.5b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacture of the finished product - Minor change in the manufacture of MANGES - FINISHED PRODUCT - COMEI COME					
B.II.b.5.B.B.Ib.5.B - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-product - Manufacture - Change in the manufacturi - B.II.b.3.B.II.b.3.B - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi - B.II.b.3.B.II.b.3.B - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturi - B.II.2.2 B.II.2.2 II.1.2.1 QUALITY CHANGES - CEPTSEMONDGRAPHS - Change BORDER WITH - B.II.2.2 B.II.2.2 II.1.2.1 QUALITY CHANGES - CEPTSEMONDGRAPHS - Change BORDER WITH - B.II.2.2 B.II.2.2 II.1.2.1 QUALITY CHANGES - CEPTSEMONDGRAPHS - Change BORDER WITH - B.II.2.2 B.II.2.2 II.1.2.1 QUALITY CHANGES - CEPTSEMONDGRAPHS - Change BORDER WITH - B.II.2.2 B.II.2.2 II.1.2.1 QUALITY CHANGES - CEPTSEMONDGRAPHS - CHANGES - CEPTSEMONDGRAPHS - CHANGES - CEPTSEMONDGRAPHS - CHANGES - CEPTSEMONDGRAPHS - CHANGES - COMBI COMED COMED COMED COMED COMBI COMED COMBI COMED COATED SIMG/8000 BOS6/23T, 6059/23T UIMTED VIATRIS B.II.2.2 B.II.2.2 - UULITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacture of the finished product - Minor changes to an approved test proceedure for the finished product - Manufacture of the finished product, including an intermediate used in the manufacture of the finished product - Minor changes to an approved test proceedure for the finished product - Manufacture - Change in the manufacturing process of the finished product, including an intermediate in the manufacture of the finished product - Minor changes to an approved test proceedure for the finished product - Manufacture - Change in the manufacturing process of the finished product - Minor changes to an approved test proceedure for the finished product - Manufacture - Change in the manufacturing process of the finished product - Minor changes to an approved test proceedure for the finished product - Manufacture - Change in the name and/or address of the marketing authorisation holder TUTECVI COATED DEASTINIB / TEVA / TABLET, FILM COATED SeG					
TUTECVI TUTECVI TUTECVI TUTECVI TUTECVI Control finished product - Manufacture - Change in the manufacturi B III.3.a.8 III.8.3.a - QUALITY TUTECVI TUTECVI TUTECVI COMBI TABLET, TABLET, FILM BIID.3.a & BIID.3.a - QUALITY TUTECVI TUTECVI TUTECVI COMBI CANOSSAM BIID.3.a & BIID.3.a - QUALITY COMBI TABLET, TABLET, FILM BIID.3.a & BIID.3.a & COMPUCT - Manufacture - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the manufacture of the finished product - Minor change in the					
TUTECVI TUTECVI Bill 5.3 b Bill 5.3 b Bill 5.3 c DUALITY CHANGES - FINSHED PRODUCT - Manufacture Change in the manufacturi Bill 5.3 a DUALITY CHANGES - FINSHED PRODUCT - Manufacture CHANGES - FINSHED PRODUCT - Manufacture CHANGES - FINSHED PRODUCT - Manufacture Column Bill 7.2 a TUTECVI CHANGES - FINSHED PRODUCT - Manufacture Bill 7.2 a DUALITY CHANGES - FINSHED PRODUCT - Manufacture CHANGES - FINSHED PRODUCT - Manufacture Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product, including an intermediate used in the manufacture of the finished product, including an intermediate used in the manufacture of the finished product, including an intermediate used in the manufacture of the finished product, including an intermediate used in the manufacture of the finished product, including an intermediate used in the manufacture of the finished product. COATED SOMG/850M 6058/23T, 6059/23T VIATRIS G G058/23T, 6059/23T VIATRIS Bill 3.2 a TUTECVI TUTECVI COMBI G058/23T, 6059/23T Bill 3.2 a TUTECVI TUTECVI COMBI G058/23T, 6059/23T UIATRIS G G058/23T, 6059/23T UIATRIS Bill 3.2 a TUTECVI COMBI TABLET, FILM FILM CAATED COATED G058/23T, 6059/23T UIATRIS A1 A					
CHANGES - FINSHED PRODUCT - Manufacture - Change in the manufacturi B.II.b.3a - UJALITY CHANGES - FINSHED PRODUCT - Manufacture - Change in the manufacturi B.II.b.3a - UJALITY CHANGES - FINSHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of B.II.6.2.a & I.I.d.2.a - QUALITY CHANGES - FINSHED PRODUCT - Control finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the marketing authorisation holder TUTECVI COMBI TABLET, TABLET, TABLET, FILM FILM FILM FILM FILM FILM FILM FILM					
TUTECVI					
TUTECVI					
Billb.3a Billb.3a - DUALTY CHANGES - FINISHED PRODUCT - Manufactura - Change in the manufacturi Billb.2a - Billb.3a - CUALTY CHANGES - CEPTEEMONOGRAPHS - Change to comply with Ph. Eur. or with Billb.3a - DUALTY CHANGES - FINISHED PRODUCT - Manufactura - Change in the manufacturing process of the finished product - Induing - Change in the manufacturing process of the finished product - Induing - Change in the manufacturing process fill - Control of finished product - Change in the manufacturing process fill - Control of finished product - Change in the manufacturing process fill - Control of finished product - Change in test procedure for the finished product - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process of the finished product - Minor change in the manufacturing process COMBI COMBI COMBI COMBI TABLET, FILM COMBI COATED SOMG/1000 BoSZ23T, 6055/23T TEVA BY ASATINIB MG DASATINIB					
Manufacture - Change in the manufacturi Bill 2 z Bill: 2 z Bill: 2 z GUALTY CHANGES - CEPTERMONOGRAPHS - Change to comply with Ph. Eur. or with Bill: 3 a - QUALTY 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. Bill: 2.3 a - QUALTY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process. Bill: 2.3 a - QUALTY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process. Bill: 2.3 a - QUALTY CHANGES - FINISHED PRODUCT - Manufacture for the finished product - Minor changes to an approved test product. Including an intermediate used in the manufacturing process of the finished product - Minor changes to an approved test product. Including an intermediate used in the manufacturing process of the finished product. Including an intermediate used in the manufacture of the finished product. Including an intermediate used in the manufacture of the finished product. Minor changes to an approved test product. Minor changes to the marketing authorisation holder DASATINIB /TEVA A1 A 1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder DASATINIB /TEVA S903/23T TEVA BV A1 A 1 - ADMINISTRATIVE CHANGES - Change					
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			5904/23T	TEVA BV	

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PROGRAF CAPSULE, HARD 5MG	PROGRAF CAPSULE, HARD 5MG	5894/23T	ASTELLAS PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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)*
RIVAROLT O TABLET, FILM COATED 15MG	RIVAROLT O 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
RIVAROLT O TABLET, FILM COATED 2.5MG	RIVAROLT O 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
RIVAROLT O TABLET, FILM COATED 20MG	RIVAROLT O 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

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RIVAROLT O TABLET, FILM COATED 10MG	RIVAROLT O 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 ARZNEIMITTE L 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	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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
CISATRAC URIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	CISATRAC URIUM 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
CISATRAC URIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	CISATRAC URIUM 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/0.1M L	VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1M L	5884/23T	ABBVIE PHARMACEU TICALS 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 PARADIS	BOTOX POWDER FOR SOLUTION FOR INJECTION 50 UNITS PARADIS	5885/23T	ABBVIE PHARMACEU TICALS 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) A.1 A.1 - ADMINISTRATIVE
VAGINAL CAPSULE, HARD	VAGINAL CAPSULE, HARD	6300/23T	FREZYDERM S.A.	CHANGES - Change in the name and/or address of the marketing authorisation holder A.5.b A.5.b - ADMINISTRATIVE
ROSUVAST ATIN ACCORD TABLET, FILM	ROSUVAST ATIN ACCORD TABLET, FILM	5654/23T	ACCORD HEALTHCARE S.L.U	A.5.D A.5.D - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The

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FOR INFUSIONFOR INFUSIONTICAL T561/23T, 7562/23T,TICAL LABORATORIArticles 45 or 46 of Regulation1G/100ML1G/100ML7561/23T, 7562/23T, 7563/23TLABORATORI ES SA1901/2006 - Implementation of wording agreed by the competent authorityAZACITIDI NE/STADAAZACITIDI NE/STADAB.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 siteSUSPENSI ON FOR INJECTION7049/23TLAGB.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS					
INFUSIONINFUSION7561/23T, 7562/23T, 7563/23TLABORATORI ES SA1901/2006 - Implementation of wording agreed by the competent authorityAZACITIDIAZACITIDINE/STADANE/STADAPOWDERPOWDERFORFORSUSPENSISUSPENSION FORON FORINJECTIONINJECTION25MG/ML25MG/ML7049/23TLABORATORIBIIL.1.a.2B.III.1.a.2 - QUALITYCHANGES - CEP/TSE/MONOGRAPHS					
1G/100ML1G/100ML7563/23TES SAagreed by the competent authorityAZACITIDIAZACITIDINE/STADANE/STADAPOWDERPOWDERFORFORSUSPENSISUSPENSION FORON FORINJECTIONINJECTION25MG/ML25MG/ML7049/23TL AGB.II.1.a.2 B.III.1.a.2 - QUALITYCHANGES - CEP/TSE/MONOGRAPHS	-	-	7561/23T. 7562/23T.	-	
AZACITIDI NE/STADA POWDER FOR SUSPENSIAZACITIDI NE/STADA POWDER FOR SUSPENSIB.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 siteNJECTION 25MG/ML7049/23TL AGAZYTER EYEEYELABORATOIR					
POWDER FOR SUSPENSIPOWDER FOR SUSPENSIPOWDER FOR SUSPENSICHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging siteON FOR INJECTION 25MG/ML7049/23TL AGB.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS	AZACITIDI	AZACITIDI			
FOR SUSPENSI ON FOR INJECTIONFOR SUSPENSI ON FOR 1NJECTIONAll the second and the se	. –				
SUSPENSI ON FOR INJECTION 25MG/MLSUSPENSI ON FOR 25MG/MLSUSPENSI ON FOR TO49/23Tof a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging siteAZYTER EYEAZYTER EYEAZYTER EYEB.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS	-				
ON FOR INJECTIONON FOR INJECTIONSTADAthe manufacturing process of the finished product - Secondary packaging site25MG/ML25MG/ML7049/23TL AGsiteAZYTER EYEAZYTER EYELABORATOIRB.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS	-	-			
INJECTIONINJECTIONARZNEIMITTEfinished product - Secondary packaging25MG/ML25MG/ML7049/23TL AGsiteAZYTERAZYTEREYEB.III.1.a.2 B.III.1.a.2 - QUALITYEYEEYELABORATOIRCHANGES - CEP/TSE/MONOGRAPHS				STADA	
25MG/ML25MG/ML7049/23TL AGsiteAZYTER EYEAZYTER EYEB.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS				-	
AZYTER AZYTER EYE B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS			7049/23T		
EYE EYE LABORATOIR CHANGES - CEP/TSE/MONOGRAPHS					
DROPS, DROPS, 5867/23T, 5868/23T ES THEA - Submission of a new or updated Ph.				LABORATOIR	
	DROPS,	DROPS,	5867/23T, 5868/23T	ES THEA	- Submission of a new or updated Ph.

	1	1	1	1
SOLUTION	SOLUTION			Eur. Certificate of suitability or deletion
15MG/G	15MG/G			of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
				to the relevant Ph. Eur. Monograph -
				Updated certificate from an already
				approved manufacturer
				C.I.5.z C.I.5.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
METHYCO BAL	METHYCO BAL		MEDILINK	MEDICINAL PRODUCTS - Change in
TABLET	TABLET		PHARMACEU	the legal status of a medicinal product for centrally authorised products - Other
500MCG	500MCG	6318/23T	TICALS LTD	variation
30010100	30010100	0310/231		B.II.b.3.b B.II.b.3.b - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change in the
PIPERACIL	PIPERACIL			manufacturing process of the finished
LIN/TAZOB	LIN/TAZOB			product, including an intermediate used
ACTAM	ACTAM			in the manufacture of the finished
KABI	KABI			product - Substantial changes to a
POWDER	POWDER			manufacturing process that may have a
FOR	FOR			significant impact on the quality, safety
SOLUTION	SOLUTION			and efficacy of the medicinal product
FOR	FOR		FRESENIUS	B.II.b.z B.II.b.z - QUALITY CHANGES -
INFUSION	INFUSION	207/227 208/227	KABI HELLAS A.E.	FINISHED PRODUCT - Manufacture -
2G/0.25G	2G/0.25G	307/23T, 308/23T	A.E.	Other variation B.II.b.3.b B.II.b.3.b - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change in the
PIPERACIL	PIPERACIL			manufacturing process of the finished
LIN/TAZOB	LIN/TAZOB			product, including an intermediate used
ACTAM	ACTAM			in the manufacture of the finished
KABI	KABI			product - Substantial changes to a
POWDER	POWDER			manufacturing process that may have a
FOR	FOR			significant impact on the quality, safety
SOLUTION	SOLUTION			and efficacy of the medicinal product
FOR INFUSION	FOR INFUSION		FRESENIUS KABI HELLAS	B.II.b.z B.II.b.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture -
4G/0.5G	4G/0.5G	309/23T, 310/23T	A.E.	Other variation
			1	B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
NETAXAN	NETAXAN			the manufacturing process of the active
EYE	EYE			substance For an excipient - European
DROPS, SOLUTION	DROPS, SOLUTION			Pharmacopoeial Certificate of Suitability
(3MG/1MG)	(3MG/1MG)			to the relevant Ph. Eur. Monograph - Updated certificate from an already
/ML	(SING/TNG) /ML	6253/23T	SIFI S.P.A	approved manufacturer
<u> </u>				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
NETAXAN	NETAXAN			Eur. Certificate of suitability or deletion
EYE	EYE			of Ph. Eur. certificate of suitability: For
DROPS,	DROPS,			an active substance For a starting
SOLUTION	SOLUTION			material/reagent/intermediate used in
IN SINGLE-	IN SINGLE-			the manufacturing process of the active
DOSE CONTAINE	DOSE CONTAINE			substance For an excipient - European Pharmacopoeial Certificate of Suitability
R	R			to the relevant Ph. Eur. Monograph -
(3MG/1MG)	(3MG/1MG)			Updated certificate from an already
/ML	/ML	6254/23T	SIFI S.P.A	approved manufacturer
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				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 -
NETAXAN EYE DROPS, SOLUTION (3MG/1MG) /ML	NETAXAN EYE DROPS, SOLUTION (3MG/1MG) /ML	2324/23T	SIFI S.P.A	New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
				B.III.1.a.5 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
NETAXAN EYE DROPS, SOLUTION IN SINGLE- DOSE	NETAXAN EYE DROPS, SOLUTION IN SINGLE- DOSE			material/reagent/intermediate used 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
CONTAINE R (3MG/1MG) /ML	CONTAINE R (3MG/1MG) /ML	2325/23T	SIFI S.P.A	medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free
PANMIGRA N TABLET, FILM COATED	PANMIGRA N TABLET, FILM COATED		GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ ΠΡΟΙΟΝΤΑ ΥΓΕΙΑΣ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩ ΠΗ ΑΝΩΝΥΜΗ ΕΤΑΙΡΕΙΑ (GSK CH ΕΛΛΑΣ	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
250MG/250 MG/65MG DICLAC 75	250MG/250 MG/65MG DICLAC 75	5970/23T	ΜΟΝΟΠΡΟΣΩ ΠΗ Α.Ε.)	Updated certificate from an already approved manufacturer
ID HEXAL TABLET, PROLONG ED- RELEASE 75MG	ID HEXAL TABLET, PROLONG ED- 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	BRADIREM TABLET, FILM COATED		REMEDICA	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the
7.5MG BRADIREM TABLET, FILM	7.5MG BRADIREM TABLET, FILM	5774/23T 5775/23T	LTD REMEDICA LTD	MAH 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
LENALIDO MIDE NORAMED A CAPSULE, HARD 25MG	LENALIDO MIDE NORAMED A 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
LENALIDO MIDE NORAMED A CAPSULE, HARD 5MG	LENALIDO MIDE NORAMED A 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
LENALIDO MIDE NORAMED A CAPSULE, HARD 15MG	LENALIDO MIDE NORAMED A 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
				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
				B.II.b.2.c.1 B.II.b.2.c.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
LENALIDO	LENALIDO			Manufacture - Change to importer,
MIDE	MIDE			batch release arrangements and quality
NORAMED	NORAMED			control testing of the finished product -
A	A			Replacement or addition of a
CAPSULE,	CAPSULE,			manufacturer responsible for
HARD	HARD	4040/007 4040/007		importation and/or batch release - Not
10MG	10MG	4848/23T, 4849/23T	NORAMEDA	including batch control/testing
				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
OXIS	OXIS			active substance, starting material,
TURBUHAL	TURBUHAL			reagent or intermediate used in the
ER	ER			manufacture of the active substance
POWDER	POWDER			(where specified in the technical
FOR	FOR			dossier) where no Ph. Eur. Certificate of
INHALATIO	INHALATIO			Suitability is part of the approved
N	N			dossier; or a manufacturer of a novel
4.5MCG/DO	4.5MCG/DO		ASTRAZENEC	excipient (where specified in the
SE	SE	7373/23T, 7374/23T	A AB	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
				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
OXIS	OXIS			active substance, starting material,
TURBUHAL	TURBUHAL			reagent or intermediate used in the
ER	ER			manufacture of the active substance
POWDER	POWDER			(where specified in the technical
FOR	FOR			dossier) where no Ph. Eur. Certificate of
INHALATIO	INHALATIO			Suitability is part of the approved
Ν	Ν			dossier; or a manufacturer of a novel
9MCG/DOS	9MCG/DOS		ASTRAZENEC	excipient (where specified in the
E	E	7371/23T, 7372/23T	A AB	technical dossier)
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				C.I.2.a C.I.2.a - SAFETY, EFFICACY,
DIAZEM TABLET 60MG	DIAZEM TABLET 60MG	7095/23T	MEDOCHEMIE	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH B.II.b.1.e B.II.b.1.e - QUALITY
REPRAT GAST TABLET, GASTRO- RESISTAN T 20MG	REPRAT GAST TABLET, GASTRO- RESISTAN T 20MG	7457/23T	DELORBIS PHARMACEU TICALS LTD	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
FESOTERO DINE ACCORD TABLET, PROLONG ED- RELEASE 8MG	FESOTERO DINE ACCORD TABLET, PROLONG ED- 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
FESOTERO DINE ACCORD TABLET, PROLONG ED- RELEASE 4MG	FESOTERO DINE ACCORD TABLET, PROLONG ED- 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	B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to 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 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
				B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermediate used in the manufacturing process of the active
				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
PANTOPRA	PANTOPRA			an active substance For a starting material/reagent/intermediate used in
ZOLE DELORBIS	ZOLE DELORBIS			the manufacturing process of the active substance For an excipient - European
TABLET, GASTRO-	TABLET, GASTRO-		DELORBIS	Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
RESISTAN T 40MG	RESISTAN T 40MG	7497/23T, 7498/23T, 7499/23T	PHARMACEU TICALS LTD	Updated certificate from an already approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
PIRFENIDO NE MSN	PIRFENIDO NE MSN			the manufacturing process of the active substance For an excipient - European
TABLET, FILM	TABLET, FILM		MSN LABS	Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
COATED 267MG	COATED 267MG	6391/23T	EUROPE LIMITED	Updated certificate from an already approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
PIRFENIDO	PIRFENIDO			material/reagent/intermediate used in the manufacturing process of the active
NE MSN TABLET, FILM	NE MSN TABLET, FILM		MSN LABS	substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
COATED 801MG	COATED 801MG	6390/23T	EUROPE	Updated certificate from an already approved manufacturer
				C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of human medicinal products intended to implement the outcome of a
EVECET TABLET,	EVECET TABLET,			procedure concerning PSUR or PASS, or the outcome of the assessment done
PROLONG ED-	PROLONG ED-		PHARMATHE	by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
RELEASE 3MG	RELEASE 3MG	5034/23T	N S.A.	agreed by the competent authority

EVECET TABLET, PROLONG ED- RELEASE 8MG	EVECET TABLET, PROLONG ED- RELEASE 8MG	5032/23T	PHARMATHE N 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, PROLONG ED- RELEASE 4MG	EVECET TABLET, PROLONG ED- RELEASE 4MG	5033/23T	PHARMATHE N 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, PROLONG ED- RELEASE 2MG	EVECET TABLET, PROLONG ED- RELEASE 2MG	5035/23T	PHARMATHE N 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- RESISTAN T 40MG	REPRAT TABLET, GASTRO- RESISTAN T 40MG	7449/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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- RESISTAN T 20MG	REPRAT TABLET, GASTRO- RESISTAN T 20MG	7450/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 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)*
NIFELAT LA TABLET, PROLONG ED- RELEASE <u>60MG</u>	NIFELAT LA TABLET, PROLONG ED- 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, PROLONG ED- RELEASE 30MG	NIFELAT LA TABLET, PROLONG ED- 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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
BORTEZO MIB/STADA SOLUTION FOR INJECTION 2.5MG/ML	BORTEZO MIB/STADA SOLUTION FOR INJECTION 2.5MG/ML	5826/23T	STADA ARZNEIMITTE L 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
LEVOTHYR OXINE ACCORD TABLET 50MCG	LEVOTHYR OXINE 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
LEVOTHYR OXINE ACCORD TABLET 100MCG	LEVOTHYR OXINE ACCORD TABLET	8400/22T	ACCORD HEALTHCARE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
100MCG LEVOTHYR OXINE ACCORD	100MCG LEVOTHYR OXINE ACCORD	8400/22T 8402/22T	S.L.U ACCORD HEALTHCARE S.L.U	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

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TABLET	TABLET			MEDICINAL PRODUCTS - Change(s)
25MCG	25MCG			in the Summary of Product
				Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
				medicinal products following
				assessment of the same change for the
				reference product - Implementation of
				change(s) for which no new additional
				data is required to be submitted by the MAH
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate 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 -
VOLTAREN	VOLTAREN			Stability - Change in the re-test
SR	SR			period/storage period or storage
SUSTAINE	SUSTAINE			conditions of the active substance
D	D			where no Ph. Eur. Certificate of
RELEASE	RELEASE		NOVARTIS	Suitability covering the retest period is
TABLETS	TABLETS	4744/23T, 4745/23T,	IRELAND	part of the approved dossier - Re-test
75MG	75MG	4746/23T	LIMITED	period/storage period -
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - Eur
				B.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 -
VOLTAREN	VOLTAREN			Stability - Change in the re-test
SR	SR			period/storage period or storage
SUSTAINE	SUSTAINE			conditions of the active substance
D	D			where no Ph. Eur. Certificate of
RELEASE	RELEASE		NOVARTIS	Suitability covering the retest period is
TABLETS	TABLETS	4744/23T, 4745/23T,	IRELAND	part of the approved dossier - Re-test
75MG	75MG	4746/23T	LIMITED	period/storage period -
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
TABLET, GASTRO-	TABLET, GASTRO-		NOVARTIS	- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
RESISTAN	RESISTAN	4738/23T, 4739/23T,	IRELAND	of Ph. Eur. certificate of suitability: For
T 50MG	T 50MG	4730/231, 4739/231, 4740/23T	LIMITED	an active substance For a starting
	1 0000			an active cubotaneer of a starting

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				conditions of the active substance
				where no Ph. Eur. Certificate of
				Suitability covering the retest period is part of the approved dossier - Re-test
				period/storage period -
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - Eur
				B.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
	VOLTAREN			CHANGES - ACTIVE SUBSTANCE -
VOLTAREN RETARD	RETARD			Stability - Change in the re-test
SUSTAINE	SUSTAINE			period/storage period or storage conditions of the active substance
D	D			where no Ph. Eur. Certificate of
RELEASE	RELEASE		NOVARTIS	Suitability covering the retest period is
TABLETS	TABLETS	4741/23T, 4742/23T,	IRELAND	part of the approved dossier - Re-test
100MG	100MG	4743/23T	LIMITED	period/storage period -
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
TOPIRAMA	TOPIRAMA			material/reagent/intermediate used in
TE	TE			the manufacturing process of the active
AUROBIND	AUROBIND			substance For an excipient - European
O TABLET,	O TABLET,		AUROBINDO	Pharmacopoeial Certificate of Suitability
FILM	FILM		PHARMA	to the relevant Ph. Eur. Monograph -
COATED	COATED		(MALTA)	Updated certificate from an already
200MG	200MG	6015/23T	LIMITED	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
TOPIRAMA	TOPIRAMA			material/reagent/intermediate used in
TE	TE			the manufacturing process of the active
				substance For an excipient - European
O TABLET, FILM	O TABLET, FILM		AUROBINDO PHARMA	Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
			(MALTA)	Updated certificate from an already
50MG	50MG	6017/23T		approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
TOPIRAMA	TOPIRAMA			of Ph. Eur. certificate of suitability: For
TE	TE			an active substance For a starting
AUROBIND O TABLET,			AUROBINDO	material/reagent/intermediate used in
FILM	O TABLET, FILM		PHARMA	the manufacturing process of the active substance For an excipient - European
COATED	COATED		(MALTA)	Pharmacopoeial Certificate of Suitability
100MG	100MG	6016/23T	LIMITED	to the relevant Ph. Eur. Monograph -
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				Updated certificate from an already
				approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
TOPIRAMA	TOPIRAMA			material/reagent/intermediate used in
TE	TE			the manufacturing process of the active
AUROBIND	AUROBIND			substance For an excipient - European
O TABLET,	O TABLET,		AUROBINDO	Pharmacopoeial Certificate of Suitability
FILM	FILM		PHARMA	to the relevant Ph. Eur. Monograph -
COATED	COATED		(MALTA)	Updated certificate from an already
25MG	25MG	6018/23T	LIMITED	approved manufacturer
20110	201110	0010/201		C.I.11.b C.I.11.b - SAFETY,
				EFFICACY, PHARMACOVIGILANCE
				CHANGES - HUMAN AND
				VETERINARY MEDICINAL
				PRODUCTS - Introduction of. or
PENTAXIM	PENTAXIM			change(s) to, the obligations and
POWDER	POWDER			conditions of a marketing authorisation,
AND	AND			including the risk management plan -
SUSPENSI	SUSPENSI			Implementation of change(s) which
ON FOR	ON FOR			require to be further substantiated by
SUSPENSI	SUSPENSI			new additional data to be submitted by
ON FOR	ON FOR		SANOFI	the MAH where significant assessment
INJECTION	INJECTION	5240/22T	PASTEUR.	by the competent authority is required*
				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
			JOHNSON &	Urgent Safety Restriction etc.
			JOHNSON	Implementation of wording agreed by
DAKTARIN	DAKTARIN		HELLAS	the competent authority that require
CREAM 2%	CREAM 2%	3388/23T, 3389/23T,	CONSUMER	additional minor assessment, e.g.
W/W	W/W	3390/23T	AE	translations are not yet agreed upon.
				C.I.4 C.I.4 - SAFETY, EFFICACY,
DEPAKINE	DEPAKINE			PHARMACOVIGILANCE CHANGES -
CHRONO	CHRONO			HUMAN AND VETERINARY
TABLET,	TABLET,			MEDICINAL PRODUCTS - Change(s)
PROLONG	PROLONG		0.000	in the Summary of Product
ED-	ED-		SANOFI	Characteristics, Labelling or Package
RELEASE	RELEASE	1011/00T	WINTHROP	Leaflet due to new quality, preclinical,
500MG	500MG	4644/22T	INDUSTRIE.	clinical or pharmacovigilance data
AMOXAPE N	AMOXAPE N			C.I.Z C.I.Z - SAFETY, EFFICACY,
N CAPSULE,	N CAPSULE,			PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
HARD	HARD		REMEDICA	MEDICINAL PRODUCTS - Other
250MG	250MG	7772/22T	LTD	variation
AMOXAPE	AMOXAPE			C.I.z C.I.z - SAFETY, EFFICACY,
N	N		REMEDICA	PHARMACOVIGILANCE CHANGES -
CAPSULE,	CAPSULE,	7771/22T	LTD	HUMAN AND VETERINARY
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HARD	HARD			MEDICINAL PRODUCTS - Other
500MG	500MG			variation
PACLITAXE L HOSPIRA CONCENT RATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXE L HOSPIRA CONCENT RATE 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
REPRAT GAST TABLET, GASTRO- RESISTAN T 20MG	REPRAT GAST TABLET, GASTRO- RESISTAN T 20MG	7431/23T, 7432/23T, 7433/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 ror an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active 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)

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				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
TOPIRAMA TE ACCORD TABLET, FILM COATED 25MG	TOPIRAMA TE 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
TOPIRAMA TE ACCORD TABLET, FILM COATED 25MG	TOPIRAMA TE 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
TOPIRAMA TE ACCORD TABLET, FILM COATED 200MG	TOPIRAMA TE 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
TOPIRAMA TE ACCORD TABLET, FILM COATED 200MG	TOPIRAMA TE 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
				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)
				CHANGES - FINISHED PRODUCT -
TOPIRAMA TE	TOPIRAMA TE			Container closure system - Change in the specification parameters and/or
ACCORD	ACCORD			limits of the immediate packaging of the
TABLET, FILM	TABLET, FILM		ACCORD	finished product - Addition of a new specification parameter to the
COATED 100MG	COATED 100MG	6113/23T, 6114/23T	HEALTHCARE S.L.U	specification with its corresponding test method
			0.2.0	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 -
TOPIRAMA	TOPIRAMA			Container closure system - Change in
TE ACCORD	TE ACCORD			the specification parameters and/or limits of the immediate packaging of the
TABLET, FILM	TABLET, FILM		ACCORD	finished product - Addition of a new specification parameter to the
COATED	COATED		HEALTHCARE	specification with its corresponding test
100MG	100MG	6113/23T, 6114/23T	S.L.U	method B.II.e.2.c B.II.e.2.c - QUALITY
				CHANGES - FINISHED PRODUCT -
				Container closure system - Change in the specification parameters and/or
				limits of the immediate packaging of the finished product - Deletion of a non-
				significant specification parameter (e.g.
				deletion of an obsolete parameter) B.II.e.2.b B.II.e.2.b - QUALITY
TOPIRAMA	TOPIRAMA			CHANGES - FINISHED PRODUCT - Container closure system - Change in
TE	TE			the specification parameters and/or
ACCORD TABLET,	ACCORD TABLET,			limits of the immediate packaging of the finished product - Addition of a new
FILM COATED	FILM COATED		ACCORD HEALTHCARE	specification parameter to the specification with its corresponding test
50MG	50MG	6115/23T, 6116/23T	S.L.U	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
TOPIDATA	TOPIDATA			limits of the immediate packaging of the
TOPIRAMA TE	TOPIRAMA TE			finished product - Deletion of a non- significant specification parameter (e.g.
ACCORD TABLET,	ACCORD TABLET,			deletion of an obsolete parameter) B.II.e.2.b B.II.e.2.b - QUALITY
FILM	FILM		ACCORD	CHANGES - FINISHED PRODUCT -
COATED 50MG	COATED 50MG	6115/23T, 6116/23T	HEALTHCARE S.L.U	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	DENEX TABLET		MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the
100MG	100MG	5809/23T	LTD	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

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				manufacturer/importer of the 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
VANCO	VANCO			CHANGES - Deletion of manufacturing
SAPIENS	SAPIENS			sites for an active substance,
POWDER	POWDER			intermediate or finished product,
FOR	FOR			packaging site, manufacturer
SOLUTION FOR	SOLUTION FOR			responsible for batch release, site where batch control takes place, or
INFUSION	INFUSION		SAPIENS	supplier of a starting material, reagent
500MG/VIA	500MG/VIA		PHARMACEU	or excipient (when mentioned in the
L	L	7434/23T	TICALS LTD	dossier)*
				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
FLEXBUMI	FLEXBUMI			- Deletion of manufacturing sites for an
Ν	N			active substance, intermediate or
SOLUTION	SOLUTION			finished product, packaging site,
FOR	FOR		BAXALTA	manufacturer responsible for batch
INFUSION	INFUSION	2640/23T, 2641/23T,	INNOVATIONS	release, site where batch control takes
200G/L	200G/L	2642/23T, 2643/23T	GMBH	place, or supplier of a starting 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
FLEXBUMI N	FLEXBUMI N			CHANGES - FINISHED PRODUCT - Manufacture - Change in the
SOLUTION	SOLUTION			manufacturing process of the finished
FOR	FOR		BAXALTA	product, including an intermediate used
INFUSION	INFUSION	2636/23T, 2637/23T,	INNOVATIONS	in the manufacture of the finished
250G/L	250G/L	2638/23T, 2639/23T	GMBH	product - Minor change in the

ULTIMAX	ULTIMAX			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
ALTER TABLET, FILM COATED	ALTER TABLET, FILM COATED		MEDOCHEMIE	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial
200MG ULTIMAX ALTER	200MG ULTIMAX ALTER	9664/21T	LTD	updates to Mod. 3.2.S or the ASMF
TABLET, FILM COATED 200MG	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	ULTIMAX ALTER TABLET, FILM			B.I.z B.I.z - QUALITY CHANGES -
COATED 400MG ULTIMAX	COATED 400MG ULTIMAX	9665/21T	MEDOCHEMIE LTD	ACTIVE SUBSTANCE - Substantial updates to Mod. 3.2.S or the ASMF
ALTER TABLET, FILM COATED	ALTER TABLET, FILM COATED		MEDOCHEMIE	B.I.z B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Substantial
400MG	400MG	9665/21T	LTD	updates to Mod. 3.2.S or the ASMF A.7 A.7 - ADMINISTRATIVE
ADAGREL TABLET, FILM COATED 75MG	ADAGREL TABLET, FILM COATED 75MG	5441/23T	SAPIENS PHARMACEU TICALS LTD	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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/0.1M L	VISTABEL POWDER FOR SOLUTION FOR INJECTION 4 ALLERGAN UNITS/0.1M L	2588/23T	ABBVIE PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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.
BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	BOTOX POWDER FOR SOLUTION FOR INJECTION 200 UNITS	2589/23T	ABBVIE PHARMACEU TICALS S.A.	agreed wording + QRD template) 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)
FULVESTR ANT ACCORD SOLUTION FOR INJECTION IN PREFILLED SYRINGE 250MG/5ML	FULVESTR ANT 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/I NJECTION 400MG/VIA L	TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/I NJECTION 400MG/VIA L	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/I NJECTION 200MG/VIA L	TALINAC POWDER AND SOLVENT FOR SOLUTION FOR INFUSION/I NJECTION 200MG/VIA L	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

				B.III.1.a.2 B.III.1.a.2 - QUALITY
NEVIRAPIN E ACCORD TABLET, PROLONG ED- RELEASE 400MG	NEVIRAPIN E ACCORD TABLET, PROLONG ED- RELEASE 400MG	6988/23T	ACCORD HEALTHCARE S.L.U	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
SPIRONOL ACTONE ACCORD TABLET, FILM COATED 25MG	SPIRONOL ACTONE 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)
SPIRONOL ACTONE ACCORD TABLET, FILM COATED 100MG	SPIRONOL ACTONE 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)
MUCOFAL K ORANGE GRANULES FOR ORAL SUSPENSI ON 3.25G/5G SACHET	MUCOFAL K ORANGE GRANULES FOR ORAL SUSPENSI ON 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.
TRAZODO NE MC TABLET 150MG	TRAZODO NE 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
				data is required to be submitted by the MAH
TRAZODO NE MC TABLET 100MG	TRAZODO NE MC TABLET 100MG	6450/23T	MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
TRAZODO NE MC TABLET 50MG	TRAZODO NE 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
PANTOFLU X TABLET, GASTRO- RESISTAN T 40MG	PANTOFLU X TABLET, GASTRO- RESISTAN T 40MG	6891/23T	TEVA BV	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
PANTOFLU X TABLET, GASTRO- RESISTAN T 20MG	PANTOFLU X TABLET, GASTRO- RESISTAN T 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	BERINERT 3000 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 3000IU BERINERT	3534/23T	CSL BEHRING GMBH CSL BEHRING	B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES -
500	500	3531/23T	GMBH	Changes to a marketing authorisation

		1		
POWDER	POWDER			resulting from other regulatory
AND	AND			procedures - Other variation
SOLVENT	SOLVENT			
FOR	FOR			
SOLUTION	SOLUTION			
FOR	FOR			
INFUSION/I	INFUSION/I			
NJECTION	NJECTION			
500IU	500IU			
BERINERT	BERINERT			
500	500			
POWDER	POWDER			
AND	AND			
SOLVENT	SOLVENT			
FOR	FOR			
SOLUTION	SOLUTION			
FOR	FOR			B.V.z B.V.z - QUALITY CHANGES -
INFUSION/I	INFUSION/I			
				Changes to a marketing authorisation
NJECTION	NJECTION	0504/00T	CSL BEHRING	resulting from other regulatory
500IU	500IU	3531/23T	GMBH	procedures - Other variation
BERINERT	BERINERT			
2000	2000			
POWDER	POWDER			
AND	AND			
SOLVENT	SOLVENT			
FOR	FOR			
SOLUTION	SOLUTION			B.V.z B.V.z - QUALITY CHANGES -
FOR	FOR			Changes to a marketing authorisation
INJECTION	INJECTION		CSL BEHRING	resulting from other regulatory
2000IU	2000IU	3533/23T	GMBH	procedures - Other variation
BERINERT	BERINERT			
2000	2000			
POWDER	POWDER			
AND	AND			
SOLVENT	SOLVENT			
FOR	FOR			
-	-			B.V.z B.V.z - QUALITY CHANGES -
SOLUTION	SOLUTION	1	1	
ECIP				
FOR	FOR			Changes to a marketing authorisation
INJECTION	INJECTION		CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU	INJECTION 2000IU	3533/23T	CSL BEHRING GMBH	Changes to a marketing authorisation
INJECTION	INJECTION	3533/23T		Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU	INJECTION 2000IU	3533/23T		Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX	INJECTION 2000IU BERIPLEX	3533/23T		Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER	INJECTION 2000IU BERIPLEX P/N POWDER	3533/23T		Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND	INJECTION 2000IU BERIPLEX P/N POWDER AND	3533/23T		Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT	3533/23T		Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR	3533/23T		Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION	3533/23T		Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES -
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR	3533/23T	GMBH	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION FOR INJECTION	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION		GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR	3533/23T 3536/23T	GMBH	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION FOR INJECTION	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION		GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU		GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500		GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER		GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND		GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT		GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR		GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES -
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION		GMBH CSL BEHRING GMBH	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION FOR	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION FOR	3536/23T	GMBH CSL BEHRING GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION FOR INJECTION	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION FOR INJECTION		GMBH CSL BEHRING GMBH	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION FOR	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION FOR	3536/23T	GMBH CSL BEHRING GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION FOR INJECTION	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR SOLUTION FOR INJECTION	3536/23T	GMBH CSL BEHRING GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR SOLUTION FOR SOLUTION FOR INJECTION BERINERT 1500	3536/23T	GMBH CSL BEHRING GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR SOLUTION FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER	3536/23T	GMBH CSL BEHRING GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND	3536/23T	GMBH CSL BEHRING GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND SOLVENT	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND SOLVENT	3536/23T	GMBH CSL BEHRING GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND SOLVENT FOR SOLVENT FOR	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR SOLUTION FOR INJECTION	3536/23T	GMBH CSL BEHRING GMBH CSL BEHRING	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES -
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION	3536/23T	GMBH CSL BEHRING GMBH CSL BEHRING GMBH	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR SOLVENT FOR SOLUTION FOR SOLUTION FOR	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR SOLVENT FOR SOLVENT FOR SOLVENT FOR SOLVENT FOR SOLVENT FOR	3536/23T 3532/23T	GMBH CSL BEHRING GMBH CSL BEHRING GMBH	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation
INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION	INJECTION 2000IU BERIPLEX P/N POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1000IU BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION BERINERT 1500 POWDER AND SOLVENT FOR SOLUTION	3536/23T	GMBH CSL BEHRING GMBH CSL BEHRING GMBH	Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation B.V.z B.V.z - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Other variation 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/10M G	ROZOR TABLET, FILM COATED 20MG/10M G	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/10M G TOLTERAN	ROZOR TABLET, FILM COATED 10MG/10M G TOLTERAN	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
A PROLONG ED RELEASE CAPSULES 2MG	A PROLONG ED RELEASE CAPSULES 2MG	6652/23T	PHARMATHE N S.A.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TOLTERAN A PROLONG ED RELEASE CAPSULES 4MG	TOLTERAN A PROLONG ED RELEASE CAPSULES 4MG	6651/23T	PHARMATHE N 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/10M G	ROZOR TABLET, FILM COATED 20MG/10M G	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 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

				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
ROZOR	ROZOR			substance or intermediate used i
TABLET, FILM	TABLET, FILM	5570/23T, 5571/23T,		A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address
COATED	COATED	5572/23T, 5573/23T,	VIATRIS	of: a manufacturer (including where
10MG/10M G	10MG/10M G	5574/23T, 5575/23T, 5576/23T	HEALTHCARE LIMITED.	relevant quality control testing sites); or an ASMF holder; o
	0	0010/201		A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing sites for an active substance.
				intermediate or finished product,
				packaging site, manufacturer 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
SOLMUCO	SOLMUCO		IBSA	active substance, starting material, reagent or intermediate used in the
L SYRUP 20MG/ML	L SYRUP 20MG/ML	7230/23T, 7231/23T, 7232/23T	FARMACEUTI CI ITALIA SRL	manufacture of the active substance (where specified in the technical doss
				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
ROLENIUM	ROLENIUM			State - Change to comply with an update of the relevant monograph of the
INHALATIO	INHALATIO			Ph. Eur. or national pharmacopoeia of a
N POWDER,	N POWDER,			Member State B.I.b.2.a B.I.b.2.a - QUALITY
PRE-	PRE-			CHANGES - ACTIVE SUBSTANCE -
DISPENSE D	DISPENSE D		ELPEN	Control of active substance - Change in test procedure for active substance or
(50+250)M	(50+250)M	4845/22T, 4846/22T,	PHARMACEU	starting material/reagent/intermediate
CG/DOSE	CG/DOSE	4847/22T, 4848/22T	TICAL CO INC	used in the manufacturing process of

(50+100)M CG/DOSE BRUFEDOL TABLET, FILM COATED	(50+100)M CG/DOSE BRUFEDOL TABLET, FILM COATED	4849/22T, 4850/22T, 4851/22T, 4852/22T	PHARMACEU TICAL CO INC VIATRIS HEALTHCARE	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
ROLENIUM INHALATIO N POWDER, PRE- DISPENSE D	ROLENIUM INHALATIO N POWDER, PRE- DISPENSE D		ELPEN	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
ROLENIUM INHALATIO N POWDER, PRE- DISPENSE D (50+500)M CG/DOSE	ROLENIUM INHALATIO N POWDER, PRE- DISPENSE D (50+500)M CG/DOSE	4841/22T, 4842/22T, 4843/22T, 4844/22T	ELPEN PHARMACEU TICAL CO INC	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 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

				Pharmacopoeial Certificate of Suitability
				to the relevant Ph. Eur. Monograph -
				Updated certificate from an already approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermediate used in
BRUFEDOL	BRUFEDOL			the manufacturing process of the active substance For an excipient - European
TABLET,	TABLET,			Pharmacopoeial Certificate of Suitability
FILM COATED	FILM COATED		VIATRIS HEALTHCARE	to the relevant Ph. Eur. Monograph - Updated certificate from an already
400MG	400MG	5710/23T, 5711/23T	LIMITED.	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in the manufacturing process of the active
BRUFEDOL	BRUFEDOL			substance For an excipient - European
TABLET, FILM	TABLET, FILM		VIATRIS	Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
COATED	COATED		HEALTHCARE	Updated certificate from an already
200MG	200MG	5706/23T, 5707/23T	LIMITED.	approved manufacturer 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
				C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet 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
TEMELOR SOLUTION	TEMELOR SOLUTION			Leaflet of a generic/hybrid/biosimilar medicinal products following
FOR	FOR			assessment of the same change for the
INJECTION 4MG/ML	INJECTION 4MG/ML	9134/22T, 9135/22T	MEDOCHEMIE LTD	reference product - Implementation of change(s)
SUGAMMA	SUGAMMA			B.II.b.5.z B.II.b.5.z - QUALITY
DEX/PHAR MAZAC	DEX/PHAR MAZAC			CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process
SOLUTION	SOLUTION	5075/00T 5070/00T		tests or limits applied during the
FOR INJECTION	FOR INJECTION	5075/23T, 5076/23T, 5077/23T, 5078/23T,	PHARMAZAC	manufacture of the finished product B.II.d.1.a B.II.d.1.a - QUALITY
100 MG/ML	100 MG/ML	5079/23T, 5080/23T	S.A.	CHANGES - FINISHED PRODUCT -

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				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 SUSPENSI ON	GAVISCON DOUBLE ACTION ORAL SUSPENSI ON	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 MEDICATE D PLASTER 200MG	NUROFEN DURANCE MEDICATE D 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	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority

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MELOX TABLET 15MG	MELOX TABLET 15MG	4786/23T	MEDOCHEMIE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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, CHEWABL E 100MG	THELMOX TABLET, CHEWABL E 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
AMIODARO NE TABLET 200MG	AMIODARO NE TABLET 200MG	7190/23T	MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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
PROCARDI N TABLET, FILM COATED 75MG	PROCARDI N TABLET, FILM COATED 75MG	4670/23T	MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional

				data is required to be submitted by the
				MAH
				A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product, packaging site, manufacturer
				responsible for batch release, site
				where batch control takes place, or
MELOX	MELOX			supplier of a starting material, reagent
TABLET	TABLET		MEDOCHEMIE	or excipient (when mentioned in the
7.5MG	7.5MG	4508/23T	LTD	dossier)*
				A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer
				responsible for batch release, site
				where batch control takes place, or
MELOX	MELOX			supplier of a starting material, reagent
TABLET 15MG	TABLET 15MG	4507/23T	MEDOCHEMIE	or excipient (when mentioned in the dossier)*
131010		TJU1/2J1		B.II.b.2.a B.II.b.2.a - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change to importer,
OXYNORM	OXYNORM		MUNDIPHARM	batch release arrangements and quality
CAPSULE,	CAPSULE,			control testing of the finished product -
HARD 10MG	HARD 10MG	7156/23T	PHARMACEU TICALS LTD	Replacement or addition of a site where batch control/testing takes place
TONIG	101010	7130/231		B.II.b.2.a B.II.b.2.a - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change to importer,
			MUNDIPHARM	batch release arrangements and quality
OXYNORM	OXYNORM			control testing of the finished product -
CAPSULE, HARD 5MG	CAPSULE, HARD 5MG	7157/23T	PHARMACEU TICALS LTD	Replacement or addition of a site where batch control/testing takes place
TIAND SIVIG	TIAND SIVIG	1157/251	TICALS LTD	B.II.b.2.a B.II.b.2.a - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change to importer,
OXYNORM	OXYNORM		MUNDIPHARM	batch release arrangements and quality
CAPSULE, HARD	CAPSULE, HARD		A PHARMACEU	control testing of the finished product - Replacement or addition of a site where
20MG	20MG	7155/23T	TICALS LTD	batch control/testing takes place
PIPERACIL	PIPERACIL			
LIN +	LIN +			
TAZOBACT	TAZOBACT			
AM/GENER	AM/GENER			
ICS POWDER	ICS POWDER			
FOR	FOR			A.2.b A.2.b - ADMINISTRATIVE
SOLUTION	SOLUTION			CHANGES - Change in the (invented)
FOR	FOR			name of the medicinal product - for
INJECTION	INJECTION		100.00	Nationally Authorised Products
/INFUSION	/INFUSION		MYLAN	A.1 A.1 - ADMINISTRATIVE CHANGES
(2G/0.25G)/ VIAL	(2G/0.25G)/ VIAL	5929/23T, 5930/23T	IRELAND LIMITED	- Change in the name and/or address of the marketing authorisation holder
PIPERACIL	PIPERACIL	0000/201		
LIN +	LIN +			
TAZOBACT	TAZOBACT			
AM/GENER	AM/GENER			
ICS POWDER	ICS POWDER			
FOR	FOR			A.2.b A.2.b - ADMINISTRATIVE
SOLUTION	SOLUTION			CHANGES - Change in the (invented)
FOR	FOR			name of the medicinal product - for
INJECTION	INJECTION			Nationally Authorised Products
/INFUSION	/INFUSION		MYLAN	A.1 A.1 - ADMINISTRATIVE CHANGES
(4G/0.5G)/V IAL	(4G/0.5G)/V IAL	5027/23T 5020/22T	IRELAND LIMITED	- Change in the name and/or address of
IAL		5927/23T, 5928/23T		the marketing authorisation holder

CLONOTRI L TABLET CLONOTRI L TABLET REMEDICA I TABLET REMEDICA I TABLET CONOTRI L TABLET L TABLET Sel523T ITD CLONOTRI L TABLET CONOTRI L TABLET ITD CI 12 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANCES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation ZMG 2MG 3614/23T ITD CI 22 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANCES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation ZMG 3614/23T ITD CI 22 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANCES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation COSTI TABLET COSTI TABLET COSTI TABLET COSTI TABLET CI 22 - CL 2 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANCES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation COSTI TABLET COSTI TABLET COSTI TABLET COSTI TABLET COSTI TABLET TABLET COSTI TABLET COSTI TABLET COSTI TABLET CHANCES - FINISHER TOSULTION SOUTION FOR PRIBEKINE FOR PRIBEKINE T PRIBEKINE T SULTION SOUTION SOUTION SULTION SULTION SULTION SOUTION SMGAIL SAGA - ADMINISTRATIVE CHANCES - FINISHE PRODUCT - Stabiliy - Change in the name and/or address of an ans/stable product - As packaged for sale (supported by real lime data) real (supported by re					C.I.z C.I.z - SAFETY, EFFICACY,
0.5MG 0.5MG 3615/23T LTD variation CLONOTRI CLONOTRI CLONOTRI CLASTETY, EFFICACY, PHARMACOVIGLANCE CHANGES - HUMAN AND VETERINARY ZMG 3614/23T LTD Cl.2 C.1 2: ASFETY, EFFICACY, PHARMACOVIGLANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation Cl.2 C.1 2: ASFETY, EFFICACY, PHARMACOVIGLANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation Cl.2 C.1 2: ASFETY, EFFICACY, PHARMACOVIGLANCE CHANGES - HUMAN AND VETERINARY COSTI TABLET COSTI TABLET CL.2 C.1 2: ASFETY, EFFICACY, PHARMACOVIGLANCE CHANGES - HUMAN AND VETERINARY PRIBEKINE TABLET COSTI TABLET MEDICINAL PRODUCTS - Other variation TABLET TABLET MEDICINAL PRODUCTS - Other variation of the same thread product characteristics, Labelling of Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same dation of charage(s) for which no new additional thread product - NEDROLUCT - SOLUTION SOLUTION SOLUTION SOLUTION SOLUTION SOLUTION SIGGML SIGMAL SMGML 6052/23T S.ITD SLI11.b1.1 BLI.1.b.1 - QUALITY CHANGES - FINSHED PROLUCT - storage conditions of the finished product - KENDAGE in the same and/or address of a manufacture/inporter is responsible include batch release or vality control testing sites) - The activities for which the manufacture/inporter is responsible include batch release or suitability is part of the agnites attego - Change in the name and/or address of a manufacture/inporter is responsible include batch release or suitability is part of the agnorved dossery of a					
CLONOTRI L TABLET CLONOTRI L TABLET PHARMACOVIGUANCE CHANGES - HUMAN AND VETERINARY ZMG 3614/23T LTD CL2.2 a.CL2.a - SAFETY, EFICACY, WEDICINAL PRODUCTS - Other variation COSTI TABLET COSTI TABLET C.L2.a CL2.a - SAFETY, EFICACY, HUMAN AND VETERINARY FIFARMACOVIGUANCE CHANGES - HUMAN AND VETERINARY COSTI TABLET COSTI TABLET COSTI TABLET CL2.a CL2.a - SAFETY, EFICACY, HUMAN AND VETERINARY PRIBEKINE SOLUTION COSTI TABLET COSTI TABLET MEDOCHEME Characteristics, Labelling or Package Leaflet of a generic/hybridiosimilar medicinal products following assessment of the same dational drains required to be submitted by the MAH PRIBEKINE SOLUTION SOLUTION SOLUTION SMGML S064/23T LTD BL11.b1.B1L1.b1-1 - QUALITY CHANGES - FINSHED PRODUCT - SOLUTON SMGML 6092/23T S.LTD A.5.a A.5.a - ADMINSTRATIVE CHANGES - FINSHED PRODUCT - solution of the shiellife or storage conditions of the finished product - Kange in the sheellife or storage conditions of the finished product - Kange in the sheellife or storage conditions of the finished product - Kange in the name and/or address or a unardacture/inpoter of the finished product - Kange in the name and/or address or a mandacture/inpoter of the finished product (including batch) release or suitability - Change in the name and/or address or a suitability is part of the approved dossien when en Ph. Eur. CORTICA SINGHE BUY - TABLET, PROLONG SA 5.a A.5.a - ADMINISTRATIVE CHANGES - Change in t			3615/23T		
CLONOTRI LTABLET 2MG LTABLET 2MG S614/23T REMEDICA LTD HUMAN AND VETERINARY MEDICINLPRODUCTS - Other variation 2MG 3614/23T LTD C.12.a C.12.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation COSTI TABLET DMG 3864/23T LTD BIJ.1.1.b 1 - UJ.1.T.b 1 -					
2MG 2MG 3614/23T LTD variation CL12 CL2 <					HUMAN AND VETERINARY
BETALOC COK TABLET, TAB			3614/23T	-	variation
BETALOC ZOK TABLET, TAB					PHARMACOVIGILANCE CHANGES -
BETALOC BETALOC BETALOC BETALOC ZOK TABLET, TABLET, TABLET, TABLET, TABLET, 10MG 3964/23T MEDOCHEMIE MEDOCHEMIE LTD MEDOCHEMIE MEDOCHEMIE MEDOCHEMIE TABLET TABLET 10MG 3964/23T PRIBEKINE PRIBEKINE T SoluTION FOR SoluTION FOR SoluTION FOR NORIDEM NUSCTION SMG/ML 6092/23T SLTD SLTD Sale (supported by real time data) ada (supported by real time data) A.5.a ADMINISTRATIVE CHANGES CANS A.5.a - ADMINISTRATIVE CHANGES Change in the name and/or address of a manufacturer (including where relevant quality control testing sites) - The active substance Cok ZOK TABLET, TABLET					
COSTI TABLET COSTI TABLET COSTI TABLET COSTI TABLET MEDOCHEMIE Leafet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH PRIBEKINE T PRIBEKINE T PRIBEKINE T BLI.11.5.1 BLI.17.1.5 ULIT.1.5 QULITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of sale (supported by real time data) SMG/ML SMG/ML 6092/23T S 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 bath release or quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting metrial, reagent or intermediate used in the manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting metrial, reagent or intermediate used in the manufacture of the approved of substance, starting metrial, reagent or intermediate used in the manufacture of the approved of substance, starting metrial, reagent or intermediate used in the manufacture of the approved of substance, starting metrial, reagent or intermediate used in the manufacture of the approved of substance, starting metrial, reagent or intermediate used in the manufacture or of the optices of a manufacture of a novel excipient (where specified in the technical dossier) BETALOC ZOK TABLET, PROLONG BETALOC ZOK TABLET, TABLET, TABLET, TABLET, TABLET, TABLET, TABLET, TABLET, TABLET, TABLET, TABLET, TABLET, TABLET, TABLET					in the Summary of Product
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BETALOC ZOKBETALOC ZOKreagent 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)RELEASE 25MGRELEASE 25MG3999/23T, 4000/23TRECORDATI IRELAND LTDRECORDATI technical dossier)RELEASE 25MG3999/23T, 4000/23TIRELAND LTDA.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					an ASMF holder; or a supplier of the
ZOK TABLET, PROLONG ED- RELEASE 25MGZOK TABLET, PROLONG ED- 25MGTABLET, PROLONG Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)25MG25MG3999/23T, 4000/23TRECORDATI IRELAND LTDRECORDATI 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 releaseBETALOC ZOK ZOK TABLET, PROLONGBETALOC ZOKBETALOC ZOKA.5.A A.4 A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the					reagent or intermediate used in the
TABLET, PROLONG ED- RELEASE 25MGTABLET, PROLONG ED- 825MGTABLET, PROLONG 25MGTABLET, PROLONG 25MGTABLET, PROLONG 25MGTABLET, PROLONCTABLET, PROLONG					
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25MG25MG3999/23T, 4000/23TIRELAND LTDtechnical 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 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	ED-	ED-			dossier; or a manufacturer of a novel
BETALOCBETALOCZOKZOKTABLET,TABLET,PROLONGPROLONGCHANGES - Change in the name and/or address of 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	-	-	3999/23T, 4000/23T		technical dossier)
BETALOCBETALOCZOKZOKTABLET,TABLET,PROLONGPROLONG					CHANGES - Change in the name
BETALOCBETALOCZOKZOKTABLET,TABLET,PROLONGPROLONG					
BETALOCBETALOCZOKZOKTABLET,TABLET,PROLONGPROLONG					product (including batch release or
BETALOCBETALOCinclude batch releaseZOKZOK- Change in the name and/or addressTABLET,TABLET,- TABLET,PROLONGPROLONG- a supplier of the					activities for which the
BETALOCBETALOC- Change in the name and/or addressZOKZOKof: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the					include batch release
TABLET,TABLET,relevant quality control testing sites); or an ASMF holder; or a supplier of the					- Change in the name and/or address
					relevant quality control testing sites); or
RELEASE RELEASE RECORDATI reagent or intermediate used in the 100MG 100MG 3995/23T, 3996/23T IRELAND LTD manufacture of the active substance	RELEASE	RELEASE	3995/23T 3996/23T		reagent or intermediate used in the

				(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 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
BETALOC ZOK	BETALOC ZOK			manufacture of the active substance (where specified in the technical
TABLET, PROLONG	TABLET, PROLONG			dossier) where no Ph. Eur. Certificate of Suitability is part of the approved
ED- RELEASE	ED- RELEASE		RECORDATI	dossier; or a manufacturer of a novel
50MG	50MG	3997/23T, 3998/23T	IRELAND LTD	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 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
BETALOC	BETALOC			manufacture of the active substance
ZOK TABLET,	ZOK TABLET,			(where specified in the technical dossier) where no Ph. Eur. Certificate of
PROLONG ED-	PROLONG ED-			Suitability is part of the approved dossier; or a manufacturer of a novel
RELEASE 200MG	RELEASE 200MG	3993/23T, 3994/23T	RECORDATI IRELAND LTD	excipient (where specified in the technical dossier)
FESOTERO DINE	FESOTERO DINE			B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE -
ACCORD TABLET,	ACCORD TABLET,			Control of active substance - Change in test procedure for active substance or
PROLONG ED-	PROLONG ED-		ACCORD	starting material/reagent/intermediate used in the manufacturing process of
RELEASE 8MG	RELEASE 8MG	6283/23T	HEALTHCARE S.L.U	the active substance - Minor changes to an approved test procedure
			0.2.0	A.z A.z - ADMINISTRATIVE CHANGES - Other variation
				B.I.z B.I.z - Quality change - Active
SUNITINIB	SUNITINIB			substance - Other variation B.I.d.1.a.4 B.I.d.1.a.4 - QUALITY
PHARMAS CIENCE	PHARMAS CIENCE		PHARMASCIE	CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test
CAPSULE, HARD	CAPSULE, HARD	5977/23T, 5978/23T,	NCE INTERNATION	period/storage period or storage conditions of the active substance
50MG	50MG	5979/23T	AL LTD	where no Ph. Eur. Certificate of

				Suitability covering the retest period is
				part of the approved dossier - Re-test period/storage period -
				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 -
SUNITINIB PHARMAS CIENCE CAPSULE, HARD 37.5MG	SUNITINIB PHARMAS CIENCE CAPSULE, HARD 37.5MG	5980/23T, 5981/23T, 5982/23T	PHARMASCIE NCE INTERNATION AL LTD	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 PHARMAS CIENCE CAPSULE, HARD 25MG	SUNITINIB PHARMAS CIENCE CAPSULE, HARD 25MG	5983/23T, 5984/23T, 5985/23T	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 PHARMAS CIENCE CAPSULE, HARD 12.5MG	SUNITINIB PHARMAS CIENCE CAPSULE, HARD 12.5MG	5986/23T, 5987/23T, 5988/23T	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 -
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 C.I.3.a C.I.3.a - SAFETY, EFFICACY,
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

				C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package
DELIPOST TABLET, FILM COATED	DELIPOST TABLET, FILM COATED			Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
10MG	10MG	3951/23T	RAFARM S.A.	agreed by the competent authority B.I.b.2.a B.I.b.2.a - QUALITY
MODULAIR TABLET, CHEWABL E 5MG	MODULAIR TABLET, CHEWABL E 5MG	3926/23T	ELPEN PHARMACEU TICAL CO INC	CHANGES - ACTIVE SUBSTANCE - Control 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, CHEWABL E 4MG	MODULAIR TABLET, CHEWABL E 4MG	3927/23T	ELPEN PHARMACEU TICAL 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 PHARMACEU TICAL 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
AMOXAPE N CAPSULE, HARD 250MG	AMOXAPE N CAPSULE, HARD 250MG	1565/23T	REMEDICA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMOXAPE N TABLET, DISPERSIB LE 250MG	AMOXAPE N TABLET, DISPERSIB LE 250MG	1559/23T	REMEDICA	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority
AMOXAPE N TABLET, FILM	AMOXAPE N 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	COATED			in the Summary of Product
250MG	250MG			Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of 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.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
AMOXAPE	AMOXAPE			or the outcome of the assessment done
N	N			by the competent authority under
CAPSULE,	CAPSULE,			Articles 45 or 46 of Regulation
HARD	HARD		REMEDICA	1901/2006 - Implementation of wording
500MG	500MG	1566/23T	LTD	agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
AMOXAPE	AMOXAPE			or the outcome of the assessment done
N TABLET,	N TABLET,			by the competent authority under
FILM COATED	FILM COATED		REMEDICA	Articles 45 or 46 of Regulation
500MG	500MG	1563/23T	LTD	1901/2006 - Implementation of wording agreed by the competent authority
300000	300000	1303/231		C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of the assessment done
EDAMOX	EDAMOX			by the competent authority under
CAPSULE,	CAPSULE,			Articles 45 or 46 of Regulation
HARD	HARD		REMEDICA	1901/2006 - Implementation of wording
500MG	500MG	1560/23T	LTD	agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
AMOXAPE N POWDER	AMOXAPE N POWDER			procedure concerning PSUR or PASS, or the outcome of the assessment done
FOR ORAL	FOR ORAL			by the competent authority under
SUSPENSI	SUSPENSI			Articles 45 or 46 of Regulation
ON	ON		REMEDICA	1901/2006 - Implementation of wording
125MG/5ML	125MG/5ML	1561/23T	LTD	agreed by the competent authority
AMOXAPE	AMOXAPE			C.I.3.a C.I.3.a - SAFETY, EFFICACY,
N POWDER	N POWDER			PHARMACOVIGILANCE CHANGES -
FOR ORAL	FOR ORAL		REMEDICA	HUMAN AND VETERINARY
SUSPENSI	SUSPENSI	1562/23T	LTD	MEDICINAL PRODUCTS - Change(s)
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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 B.III.1.a.2 B.III.1.a.2 - QUALITY
PROMETH AZINE TABLET, FILM COATED 25MG	PROMETH AZINE TABLET, FILM COATED 25MG	7297/23T, 7298/23T	REMEDICA	B.III. 1.a.2 B.III. 1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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
PROMETH AZINE TABLET, FILM COATED 10MG	PROMETH AZINE TABLET, FILM COATED 10MG	7299/23T, 7300/23T	REMEDICA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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
BETAISOD ONA VAGINAL SUPPOSIT ORIES 200MG	BETAISOD ONA VAGINAL SUPPOSIT ORIES 200MG	2865/23T, 2866/23T, 2867/23T, 2868/23T, 2869/23T, 2870/23T	MUNDIPHARM A PHARMACEU TICALS 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

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				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 B.II.b.1.a B.II.b.1.a - QUALITY
VILDAGLIP TIN PHARMAT HEN TABLET	VILDAGLIP TIN PHARMAT HEN TABLET		PHARMATHE	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
50MG	50MG	6126/23T	N S.A.	site C.I.2.a C.I.2.a - SAFETY, EFFICACY,
MEDOPRA ZOLE GASTRO- RESISTAN T CAPSULE, HARD 20MG	MEDOPRA ZOLE GASTRO- RESISTAN T CAPSULE, HARD 20MG	6445/23T	MEDOCHEMIE LTD	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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/50	TIENAM POWDER FOR SOLUTION FOR INFUSION (500MG/50	837/23T, 838/23T, 839/23T, 840/23T,	MERCK SHARP &	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 - 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 - 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,
0MG)VIAL	0MG)VIAL	841/23T	DOHME BV	batch release arrangements and quality

				control testing of the finished product -
				Replacement or addition
				manufacturer responsible for batch release, site where batch control takes
LAMOSYNT TABLET 200MG	LAMOSYNT TABLET 200MG	6900/23T, 6901/23T, 6902/23T	CODAL- SYNTO LIMITED	place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
				 B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - Eur B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the 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
LAMOSYNT TABLET 50MG	LAMOSYNT TABLET 50MG	6906/23T, 6907/23T, 6908/23T	CODAL- SYNTO LIMITED	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

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				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.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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
LAMOSYNT	LAMOSYNT		CODAL-	place, or supplier of a starting material,
TABLET	TABLET	6903/23T, 6904/23T,	SYNTO	reagent or excipient (when mentioned in
100MG	100MG	6905/23T	LIMITED	the dossier)*
				A.7 A.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
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BREXIN	BREXIN	6858/23T, 6859/23T,	CHIESI	CHANGES - FINISHED PRODUCT -
BREXIN TABLET 20MG	BREXIN TABLET 20MG	6858/23T, 6859/23T, 6860/23T, 6861/23T, 6862/23T, 6863/23T	CHIESI HELLAS A.E.B.E.	

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				manufacture of the finished product - Other changes
				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
BINOSTO EFFERVES	BINOSTO EFFERVES			of a summary of pharmacovigilance system, changes in QPPV (including
CENT	CENT			contact details) and/or changes in the
TABLET 70MG	TABLET 70MG	6332/23T	GALENICA SA	Pharmacovigilance System Master File (PSMF) location
				A.5.b A.5.b - ADMINISTRATIVE
CLOPIDOG	CLOPIDOG			CHANGES - Change in the name and/or address of a
REL	REL			manufacturer/importer of the finished
ACCORD TABLET.	ACCORD TABLET,			product (including batch release or quality control testing sites) - The
FILM	FILM		ACCORD	activities for which the
COATED	COATED	6656/22T	HEALTHCARE	manufacturer/importer is responsible do
75MG	75MG	6656/23T	S.L.U	not include batch release 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
TIENAM	TIENAM			B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT -
POWDER	POWDER			Manufacture - Change in the batch size
FOR SOLUTION	FOR SOLUTION			(including batch size ranges) of the finis B.II.b.3.z B.II.b.3.z - QUALITY
FOR	FOR	829/23T, 830/23T,		CHANGES - FINISHED PRODUCT -
INFUSION (500MG/50	INFUSION (500MG/50	831/23T, 832/23T, 833/23T, 834/23T,	MERCK SHARP &	Manufacture - Change in the manufacturing process of the finished
0MG)VIAL	0MG)VIAL	835/23T, 836/23T	DOHME BV	product, includ
				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
TIENAM POWDER	TIENAM POWDER			CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size
FOR	FOR			(including batch size ranges) of active
SOLUTION FOR	SOLUTION FOR	829/23T, 830/23T,		substanc B.I.c.1.z B.I.c.1.z - QUALITY CHANGES
INFUSION	INFUSION	831/23T, 832/23T,	MERCK	- ACTIVE SUBSTANCE - Container
(500MG/50	(500MG/50	833/23T, 834/23T, 835/23T, 836/23T	SHARP &	closure system - Change in immediate
0MG)VIAL	0MG)VIAL	000/201,000/201	DOHME BV	packaging of the active substance -

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				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 manufacture - Change in the manufacturing process of the finished product, includ
CLOMIPRA MINE TABLET, FILM COATED 25MG	CLOMIPRA MINE 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 A.1 A.1 - ADMINISTRATIVE
AMARYL TABLET 3MG	AMARYL TABLET 3MG	4760/23T	SANOFI WINTHROP INDUSTRIE.	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
BICALUTA MIDE/RAFA RM TABLET, FILM COATED 50MG	BICALUTA MIDE/RAFA RM 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
BICALUTA MIDE/RAFA RM TABLET, FILM COATED 150MG	BICALUTA MIDE/RAFA RM 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

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				to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
REGAINE CUTANEO US SOLUTION 5% W/V	REGAINE CUTANEO US 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)
FLUTIFOR M PRESSURI SED INHALATIO N, SUSPENSI ON 125MCG/5 MCG	FLUTIFOR M PRESSURI SED INHALATIO N, SUSPENSI ON 125MCG/5 MCG	6189/23T	MUNDIPHARM A PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLUTIFOR M PRESSURI SED INHALATIO N, SUSPENSI ON 50MCG/5M CG	FLUTIFOR M PRESSURI SED INHALATIO N, SUSPENSI ON 50MCG/5M CG	6190/23T	MUNDIPHARM A PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
FLUTIFOR M PRESSURI SED INHALATIO N, SUSPENSI ON 250MCG/10 MCG PARACETA MOL	FLUTIFOR M PRESSURI SED INHALATIO N, SUSPENSI ON 250MCG/10 MCG PARACETA MOL	6188/23T	MUNDIPHARM A PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
SAPIENS SOLUTION FOR	SAPIENS SOLUTION FOR	6725/23T	SAPIENS PHARMACEU TICALS LTD	MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package

INFUSION	INFUSION			Leaflet intended to implement the
10MG/ML	10MG/ML			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
				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
ERLOTINIB	ERLOTINIB			- ACTIVE SUBSTANCE - Manufacture -
SANDOZ	SANDOZ			Change in the manufacturer of a starting
TABLET,	TABLET,	7623/22T, 7624/22T,		material/reagent/intermediate used in
FILM	FILM	7625/22T, 7626/22T,		the manufacturing process of the active
COATED	COATED	7627/22T, 7628/22T,	SANDOZ	substance or change in the
150MG	150MG	7629/22T	GMBH	manufacturer (including where r
ERLOTINIB	ERLOTINIB			B.II.d.2.a B.II.d.2.a - QUALITY
SANDOZ	SANDOZ			CHANGES - FINISHED PRODUCT -
TABLET,	TABLET,			Control of finished product - Change in
FILM	FILM		0.0.10.07	test procedure for the finished product -
COATED	COATED	5404/04T 5400/04T	SANDOZ	Minor changes to an approved test
150MG	150MG	5181/21T, 5182/21T	GMBH	procedure A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing sites for an active substance,
				intermediate or finished product,
ERLOTINIB	ERLOTINIB			packaging site, manufacturer
SANDOZ	SANDOZ			responsible for batch release, site
TABLET,	TABLET,			where batch control takes place, or
FILM	FILM			supplier of a starting material, reagent
COATED	COATED		SANDOZ	or excipient (when mentioned in the
150MG	150MG	2860/21T	GMBH	dossier)*
				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 -
ERLOTINIB	ERLOTINIB			Control of active substance - Change in
SANDOZ	SANDOZ			test procedure for active substance or
TABLET,	TABLET,			starting material/reagent/intermediate
FILM	FILM	500/22T, 501/22T,		used in the manufacturing process of
COATED	COATED	502/22T, 503/22T,	SANDOZ	the active substance - Minor changes to
150MG	150MG	504/22T	GMBH	an approved test procedure
ERLOTINIB	ERLOTINIB	941/21T, 942/21T,	SANDOZ	B.I.b.2.a B.I.b.2.a - QUALITY
SANDOZ	SANDOZ	943/21T	GMBH	CHANGES - ACTIVE SUBSTANCE -

TABLET, FILM COATED 150MG ERLOTINIB	TABLET, FILM COATED 150MG ERLOTINIB			Control 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
SANDOZ TABLET, FILM COATED 150MG	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
BETNOVAT E CREAM 0.1% W/W	BETNOVAT E CREAM 0.1% W/W	5942/23T	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
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

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				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 B.III.1.a.2 B.III.1.a.2 - QUALITY
ZOVAR TABLET, FILM COATED 80MG	ZOVAR TABLET, FILM COATED 80MG	7233/23T	REMEDICA LTD	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - 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 PALEXIA ORAL	TRACRIUM INJECTION 10MG/ML PALEXIA ORAL	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 - B.I.b.1.d B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE -
SOLUTION 20MG/ML	SOLUTION 20MG/ML	6559/23T, 6560/23T	GRUNENTHAL GMBH	Control of active substance - Change in the specification parameters and/or

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
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 RETARD TABLET, PROLONG ED- RELEASE 50MG	PALEXIA RETARD TABLET, PROLONG ED- RELEASE 50MG	6557/23T, 6558/23T	GRUNENTHAL GMBH	approved manufacturer 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
				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

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				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 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
PALEXIA RETARD	PALEXIA RETARD			material/reagent/intermediate used in the manufacturing process of the active
TABLET,	TABLET,			substance For an excipient - European
PROLONG	PROLONG			Pharmacopoeial Certificate of Suitability
ED- RELEASE	ED- RELEASE		GRUNENTHAL	to the relevant Ph. Eur. Monograph - New certificate from an already
25MG	25MG	6547/23T, 6548/23T	GMBH	approved manufacturer
				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
PALEXIA	PALEXIA			material/reagent/intermediate used in
RETARD				the manufacturing process of the active
TABLET, PROLONG	TABLET, PROLONG			substance For an excipient - European Pharmacopoeial Certificate of Suitability
ED-	ED-			to the relevant Ph. Eur. Monograph -
RELEASE	RELEASE		GRUNENTHAL	New certificate from an already
200MG	200MG	6551/23T, 6552/23T	GMBH	approved manufacturer B.I.b.1.d B.I.b.1.d - QUALITY
PALEXIA	PALEXIA			CHANGES - ACTIVE SUBSTANCE -
RETARD	RETARD			Control of active substance - Change in
TABLET, PROLONG	TABLET, PROLONG		GRUNENTHAL	the specification parameters and/or limits of an active substance, starting
ED-	ED-	6549/23T, 6550/23T	GMBH	material / intermediate / reagent used in
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RELEASE	RELEASE			the manufacturing process of the active
250MG	250MG			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
				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
PALEXIA	PALEXIA			substance For an excipient - European
TABLET,	TABLET,			Pharmacopoeial Certificate of Suitability
FILM	FILM			to the relevant Ph. Eur. Monograph -
COATED	COATED		GRUNENTHAL	New certificate from an already
100MG	100MG	6567/23T, 6568/23T	GMBH	approved manufacturer
				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
PALEXIA	PALEXIA			material/reagent/intermediate used in
RETARD	RETARD			the manufacturing process of the active
TABLET,	TABLET,			substance For an excipient - European
PROLONG	PROLONG			Pharmacopoeial Certificate of Suitability
ED-	ED-			to the relevant Ph. Eur. Monograph -
RELEASE	RELEASE	OFFE DOT OFFE DOT	GRUNENTHAL	New certificate from an already
100MG	100MG	6555/23T, 6556/23T	GMBH	approved manufacturer
				B.I.b.1.d B.I.b.1.d - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
PALEXIA	PALEXIA			Control of active substance - Change in the specification parameters and/or
ORAL	ORAL			limits of an active substance, starting
SOLUTION	SOLUTION		GRUNENTHAL	material / intermediate / reagent used in
4MG/ML	4MG/ML	6561/23T, 6562/23T	GMBH	the manufacturing process of the active
		0001/201,0002/201	Smol	and manufacturing process of the active

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				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, PROLONG ED- RELEASE 150MG	PALEXIA RETARD TABLET, PROLONG ED- 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
DULOXETI NE ACCORD GASTRO- RESISTAN T CAPSULE, HARD 30MG	DULOXETI NE ACCORD GASTRO- RESISTAN T 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
DULOXETI NE ACCORD GASTRO- RESISTAN T CAPSULE, HARD 60MG	DULOXETI NE ACCORD GASTRO- RESISTAN T 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/50 0MG)VIAL	TIENAM POWDER FOR SOLUTION FOR INFUSION (500MG/50 0MG)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
ATORVAST ATIN ACCORD TABLET, FILM	ATORVAST ATIN 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
ATORVAST ATIN ACCORD TABLET, FILM COATED 20MG	ATORVAST ATIN 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
ATORVAST ATIN ACCORD TABLET, FILM COATED 40MG	ATORVAST ATIN 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	PHARMATHE N 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	PHARMATHE N 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	PHARMATHE N 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	PHARMATHE N 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	HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 50G/L HUMAN	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 B.I.a.2.a B.I.a.2.a - QUALITY
ALBUMIN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L	6120/23T	BAXALTA INNOVATIONS GMBH	CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance

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HUMAN	HUMAN			B.I.a.2.a B.I.a.2.a - QUALITY
ALBUMIN	ALBUMIN			CHANGES - ACTIVE SUBSTANCE -
BAXALTA	BAXALTA			Manufacture - Changes in the
SOLUTION	SOLUTION			manufacturing process of the active
FOR	FOR		BAXALTA	substance - Minor change in the
INFUSION	INFUSION		INNOVATIONS	manufacturing process of the active
200G/L	200G/L	6121/23T	GMBH	substance
				B.II.d.2.a B.II.d.2.a - QUALITY
				CHANGES - FINISHED PRODUCT -
DIAZEPAM	DIAZEPAM			Control of finished product - Change in
ACCORD	ACCORD		ACCORD	test procedure for the finished product -
TABLET	TABLET	6337/23T, 6338/23T,	HEALTHCARE	Minor changes to an approved test
10MG	10MG	6339/23T, 6340/23T	S.L.U	procedure
				B.II.d.2.a B.II.d.2.a - QUALITY
				CHANGES - FINISHED PRODUCT -
DIAZEPAM	DIAZEPAM			Control of finished product - Change in
ACCORD	ACCORD		ACCORD	test procedure for the finished product -
TABLET	TABLET	6341/23T, 6342/23T,	HEALTHCARE	Minor changes to an approved test
5MG	5MG	6343/23T, 6344/23T	S.L.U	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
ALENDRO	ALENDRO			substance For an excipient - European
NIC ACID	NIC ACID			Pharmacopoeial Certificate of Suitability
ACCORD	ACCORD		ACCORD	
				to the relevant Ph. Eur. Monograph -
TABLET	TABLET	5000/00T	HEALTHCARE	Updated certificate from an already
70MG	70MG	5669/23T	S.L.U	approved manufacturer
				B.II.d.2.a B.II.d.2.a - QUALITY
				CHANGES - FINISHED PRODUCT -
				Control of finished product - Change in
				test procedure for the finished product -
BERIPLEX	BERIPLEX			Minor changes to an approved test
P/N	P/N			procedure
POWDER	POWDER			B.I.b.2.a B.I.b.2.a - QUALITY
AND	AND			CHANGES - ACTIVE SUBSTANCE -
SOLVENT	SOLVENT			Control of active substance - Change in
FOR	FOR			test procedure for active substance or
SOLUTION	SOLUTION			starting material/reagent/intermediate
FOR	FOR			used in the manufacturing process of
INJECTION	INJECTION		CSL BEHRING	the active substance - Minor changes to
500IU	500IU	5816/23T, 5817/23T	GMBH	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 -
BERIPLEX	BERIPLEX			Minor changes to an approved test
P/N	P/N			procedure
POWDER	POWDER			B.I.b.2.a B.I.b.2.a - QUALITY
AND	AND			CHANGES - ACTIVE SUBSTANCE -
SOLVENT	SOLVENT			Control of active substance - Change in
FOR	FOR			test procedure for active substance or
SOLUTION	SOLUTION			starting material/reagent/intermediate
FOR	FOR			used in the manufacturing process of
INJECTION	INJECTION		CSL BEHRING	the active substance - Minor changes to
1000IU	1000IU	5814/23T, 5815/23T	GMBH	an approved test procedure
		· · ·		C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
MYFORTIC	MYFORTIC			HUMAN AND VETERINARY
GASTRO-	GASTRO-			MEDICINAL PRODUCTS - Change(s)
RESISTAN	RESISTAN			in the Summary of Product
T COATED	T COATED		NOVARTIS	Characteristics, Labelling or Package
TABLETS	TABLETS		IRELAND	Leaflet due to new quality, preclinical,
180MG	180MG	5791/21T	LIMITED	clinical or pharmacovigilance data
100110	100000	0.01/211		similar of priantiaoovignatioo data

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MYFORTIC GASTRO- RESISTAN T COATED TABLETS 360MG	MYFORTIC GASTRO- RESISTAN T 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- RESISTAN T COATED TABLETS 180MG	MYFORTIC GASTRO- RESISTAN T 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- RESISTAN T COATED TABLETS 360MG	MYFORTIC GASTRO- RESISTAN T 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 PHARMACEU TICALS 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	BICOL TABLET, FILM	7400/00T 7404/00T	DELORBIS	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
COATED 12.5MG	COATED 12.5MG	7123/23T, 7124/23T, 7125/23T, 7126/23T	PHARMACEU TICALS LTD	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 PHARMACEU TICALS 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

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				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph New certificate from a new
				manufacturer (replacement or addition) C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
REVAMOX TABLET, FILM COATED 200MG	REVAMOX TABLET, FILM COATED 200MG	4360/23T	SAPIENS PHARMACEU TICALS LTD	medicinal products following assessment of the 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/25M G	LEVOMED TABLET 100MG/25M G	6976/23T	MEDOCHEMIE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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/10M G	LEVOMED TABLET 100MG/10M G	6977/23T	MEDOCHEMIE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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/25M G	LEVOMED TABLET 250MG/25M G	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 PHARMACEU TICALS 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 PHARMACEU TICALS 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
LEVOXACI N TABLET, FILM COATED 250MG	LEVOXACI N TABLET, FILM COATED 250MG	6209/23T	SAPIENS PHARMACEU TICALS 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
ANASTROZ OLE ACCORD TABLET, FILM COATED 1MG	ANASTROZ OLE 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 with its corresponding test method
ISOFLURA NE INHALATIO N VAPOUR, LIQUID 100% V/V	ISOFLURA NE INHALATIO N 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

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				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
ROZOR	ROZOR			starting material/reagent/in
TABLET,	TABLET,			B.I.b.1.b B.I.b.1.b - QUALITY
FILM	FILM	0070/00T 007 //207	1/147510	CHANGES - ACTIVE SUBSTANCE -
COATED	COATED	9873/22T, 9874/22T,	VIATRIS HEALTHCARE	Control of active substance - Change in
20MG/10M G	20MG/10M G	9875/22T, 9876/22T, 9877/22T, 9878/22T	LIMITED.	the specification parameters and/or limits of an active substance,
0	0	3011/221, 3010/221	EIWITED.	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
ROZOR	ROZOR			starting material/reagent/in
TABLET,	TABLET,			B.I.b.1.b B.I.b.1.b - QUALITY
FILM COATED	FILM COATED	9879/22T, 9880/22T,	VIATRIS	CHANGES - ACTIVE SUBSTANCE -
10MG/10M	10MG/10M	9879/221, 9880/221, 9881/22T, 9882/22T,	HEALTHCARE	Control of active substance - Change in the specification parameters and/or
G	G	9883/22T, 9884/22T	LIMITED.	limits of an active substance,
		,		B.II.e.1.b.2 B.II.e.1.b.2 - QUALITY
ZOLEDRO	ZOLEDRO			CHANGES - FINISHED PRODUCT -
NIC ACID	NIC ACID			Container closure system - Change in
ALTAN SOLUTION	ALTAN SOLUTION			immediate packaging of the finished product - Change in type of container or
FOR	FOR		ALTAN	addition of a new container - Sterile
INFUSION	INFUSION		PHARMACEU	medicinal products and biological/
4MG/100ML	4MG/100ML	9384/22T	TICALS S.A.	immunological medicinal products
ULCERAN	ULCERAN		MEDOCHEMIE	C.I.3.a C.I.3.a - SAFETY, EFFICACY,
TABLET,	TABLET,	6322/23T	LTD	PHARMACOVIGILANCE CHANGES -

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FILM	FILM			HUMAN AND VETERINARY
COATED	COATED			MEDICINAL PRODUCTS - Change(s)
40MG	40MG			in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of 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.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
ULCERAN	ULCERAN			or the outcome of the assessment done
TABLET,	TABLET,			by the competent authority under
FILM	FILM			Articles 45 or 46 of Regulation
COATED	COATED		MEDOCHEMIE	1901/2006 - Implementation of wording
20MG	20MG	6323/23T	LTD	agreed by the competent authority
				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
ULTRAVIST	ULTRAVIST			the manufacturing process of the active
370	370			substance For an excipient - European
SOLUTION	SOLUTION			Pharmacopoeial Certificate of Suitability
FOR	FOR			to the relevant Ph. Eur. Monograph -
INJECTION	INJECTION		BAYER	Updated certificate from an already
		1276/22T 1277/22T		,
76.9%	76.9%	1376/23T, 1377/23T	HELLAS ABEE	approved manufacturer
				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
ULTRAVIST	ULTRAVIST			the manufacturing process of the active
300	300			substance For an excipient - European
SOLUTION	SOLUTION			Pharmacopoeial Certificate of Suitability
FOR	FOR			to the relevant Ph. Eur. Monograph -
INJECTION	INJECTION		BAYER	Updated certificate from an already
62.34%	62.34%	1278/22T 1270/22T	HELLAS ABEE	approved manufacturer
02.04/0	02.04/0	1378/23T, 1379/23T	HILLEAU ADEE	approved manulaciulei

SEPTOBO RE EYE DROPS	SEPTOBO RE EYE DROPS	6124/23T, 6125/23T	COOPER PHARMACEU TICALS 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
PANTOPRA ZOLE AUROBIND O TABLET, GASTRO- RESISTAN T 40MG	PANTOPRA ZOLE AUROBIND O TABLET, GASTRO- RESISTAN T 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
PANTOPRA ZOLE AUROBIND O TABLET, GASTRO- RESISTAN T 20MG	PANTOPRA ZOLE AUROBIND O TABLET, GASTRO- RESISTAN T 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
ENTEVIRE M TABLET, FILM COATED 0.5MG	ENTEVIRE M 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
ENTEVIRE M TABLET, FILM COATED 1MG CLARIPEN GRANULES FOR ORAL	ENTEVIRE M TABLET, FILM COATED 1MG CLARIPEN GRANULES FOR ORAL	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 B.II.d.2.a B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in
SUSPENSI ON 250MG/5ML	SUSPENSI ON 250MG/5ML	7066/23T	ELPEN PHARMACEU TICAL CO INC	test procedure for the finished product - Minor changes to an approved test procedure

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NORETHIS TERONE TABLET	NORETHIS TERONE TABLET	7175/23T, 7176/23T, 7177/23T, 7178/23T,	REMEDICA	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
5MG	5MG	7177/231, 7178/231, 7179/23T, 7180/23T	LTD	release, site where bat
ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG	ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG	4423/23T	SANDOZ PHARMACEU TICALS 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 TRIACOR	ZINACEF POWDER FOR SOLUTION FOR INJECTION /INFUSION 1.5G TRIACOR	4424/23T	SANDOZ PHARMACEU TICALS 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 B.II.b.5.b B.II.b.5.b - QUALITY
TABLET, PROLONG ED- RELEASE 5MG/5MG	TABLET, PROLONG ED- RELEASE 5MG/5MG	423/23T	SANOFI WINTHROP INDUSTRIE.	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
ISOFLURA NE INHALATIO N VAPOUR, LIQUID 100% V/V	ISOFLURA NE INHALATIO N 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
				product - Minor change in the manufacturing process
ISOFLURA	ISOFLURA			B.II.d.2.d B.II.d.2.d - QUALITY
NE	NE			CHANGES - FINISHED PRODUCT -
INHALATIO	INHALATIO			Control of finished product - Change in
N VAPOUR,	N VAPOUR,		PIRAMAL	test procedure for the finished product -
		4070/22T		Other changes to a test procedure
100% V/V	100% V/V	4970/23T	CARE B.V.	(including replacement or addition) B.I.b.2.e B.I.b.2.e - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
				Control of active substance - Change in
				test procedure for active substance or
ISOFLURA	ISOFLURA			starting material/reagent/intermediate
NE	NE			used in the manufacturing process of
INHALATIO	INHALATIO			the active substance - Other changes to
N VAPOUR,	N VAPOUR,		PIRAMAL	a test procedure (including replacement
		5122/22T		or addition) for the active substance or a
100% V/V	100% V/V	5132/23T	CARE B.V.	starting material/intermediate B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
ARCHIFAR	ARCHIFAR			an active substance For a starting
POWDER	POWDER			material/reagent/intermediate used in
FOR	FOR			the manufacturing process of the active
SOLUTION	SOLUTION			substance For an excipient - European
FOR INJECTION	FOR INJECTION			Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph
/INFUSION	/INFUSION		MEDOCHEMIE	New certificate from a new
500MG	500MG	6882/23T	LTD	manufacturer (replacement or addition)
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
ARCHIFAR POWDER	ARCHIFAR POWDER			an active substance For a starting material/reagent/intermediate used in
FOR	FOR			the manufacturing process of the active
SOLUTION	SOLUTION			substance For an excipient - European
FOR	FOR			Pharmacopoeial Certificate of Suitability
INJECTION	INJECTION			to the relevant Ph. Eur. Monograph
/INFUSION	/INFUSION		MEDOCHEMIE	New certificate from a new
1G	1G	6881/23T	LTD	manufacturer (replacement or addition)
				C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar
				medicinal products following
ARESTON	ARESTON			assessment of the same change for the
TABLET,	TABLET,			reference product - Implementation of
FILM COATED	FILM COATED		MEDOCHEMIE	change(s) for which no new additional
50MG	50MG	5399/23T	LTD	data is required to be submitted by the MAH
5000	5000	0000/201		C.I.11.z C.I.11.z - SAFETY,
				EFFICACY, PHARMACOVIGILANCE
				CHANGES - HUMAN AND
				VETERINARY MEDICINAL
TRIPLIXAM	TRIPLIXAM			PRODUCTS - Introduction of, or
TABLET,	TABLET,			change(s) to, the obligations and
FILM COATED	FILM		LES	conditions of a marketing authorisation,
5MG/1.25M	COATED 5MG/1.25M		LES LABORATOIR	including the risk management plan - Other RMP changes (e.g. agreed
G/10MG	G/10MG	4079/23T	ES SERVIER	wording + template change)
TRIPLIXAM	TRIPLIXAM		LES	C.I.11.z C.I.11.z - SAFETY,
TABLET,	TABLET,		LABORATOIR	EFFICACY, PHARMACOVIGILANCE
FILM	FILM	4078/23T	ES SERVIER	CHANGES - HUMAN AND

COATED 5MG/1.25M G/5MG	COATED 5MG/1.25M	1		
	0.0.0/1.2010			VETERINARY MEDICINAL PRODUCTS - Introduction of, or
	G/5MG			change(s) to, the obligations and
				conditions of a marketing authorisation,
				including the risk management plan -
				Other RMP changes (e.g. agreed wording + template change)
				C.I.11.z C.I.11.z - SAFETY,
				EFFICACY, PHARMACOVIGILANCE
				CHANGES - HUMAN AND VETERINARY MEDICINAL
TRIPLIXAM	TRIPLIXAM			PRODUCTS - Introduction of, or
TABLET,	TABLET,			change(s) to, the obligations and
FILM COATED	FILM COATED		LES	conditions of a marketing authorisation,
10MG/2.5M	10MG/2.5M		LABORATOIR	including the risk management plan - Other RMP changes (e.g. agreed
G/10MG	G/10MG	4081/23T	ES SERVIER	wording + template change)
				C.I.11.z C.I.11.z - SAFETY,
				EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND
				VETERINARY MEDICINAL
TRIPLIXAM	TRIPLIXAM			PRODUCTS - Introduction of, or
TABLET, FILM	TABLET, FILM			change(s) to, the obligations and
			LES	conditions of a marketing authorisation, including the risk management plan -
10MG/2.5M	10MG/2.5M		LABORATOIR	Other RMP changes (e.g. agreed
G/5MG	G/5MG	4080/23T	ES SERVIER	wording + template change)
				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
	DALUDA OT			substance (where specified in the
DAMIRAST TABLET,	DAMIRAST TABLET,			technical dossier) where no Ph. Eur. Certificate of Suitability is part of the
FILM	FILM		ELPEN	approved dossier; or a manufacturer of
COATED	COATED		PHARMACEU	a novel excipient (where specified in the
500MCG	500MCG	5873/23T	TICAL CO INC	technical dossier)
POWDER	POWDER			
AND	AND			
SOLUTION	SOLUTION			
FOR	FOR		NORIDEM	B.II.b.4.z B.II.b.4.z - QUALITY
		5556/23T		
.0		0000/201		B.I.b.1.h B.I.b.1.h - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
				Control of active substance - Change in
				material / intermediate / reagent used in
				the manufacturing process of the active
CLINIMIX				substance) of a specification parameter
CLINIMIX N14G30E SOLUTION	N14G30E SOLUTION			
N14G30E SOLUTION FOR	SOLUTION FOR		BAXTER	with its corresponding test method as a
N14G30E SOLUTION	SOLUTION	704/22T	BAXTER (HELLAS) EPE	with its corresponding test method as a result of a safety or quality issue
N14G30E SOLUTION FOR	SOLUTION FOR	704/22T		with its corresponding test method as a result of a safety or quality issue B.III.1.a.5 B.III.1.a.5 - QUALITY
N14G30E SOLUTION FOR INFUSION	SOLUTION FOR INFUSION	704/22T		with its corresponding test method as a result of a safety or quality issue B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
N14G30E SOLUTION FOR INFUSION CLINIMIX N14G30E	SOLUTION FOR INFUSION CLINIMIX N14G30E	704/22T		with its corresponding test method as a result of a safety or quality issue 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
N14G30E SOLUTION FOR INFUSION	SOLUTION FOR INFUSION	704/22T		with its corresponding test method as a result of a safety or quality issue B.III.1.a.5 B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
VERACOL IM POWDER AND SOLVENT FOR SOLUTION	VERACOL IM POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 1G	5556/23T	NORIDEM ENTERPRISE S LTD	B.II.b.4.z B.II.b.4.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation 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

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				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.III.1.a.2 B.III.1.a.2 - QUALITY
CLINIMIX N14G30E SOLUTION FOR INFUSION	CLINIMIX N14G30E SOLUTION FOR INFUSION	5448/23T	BAXTER (HELLAS) EPE	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
RANOLAZI NE ELC TABLET, PROLONG ED- RELEASE 750MG	RANOLAZI NE ELC TABLET, PROLONG ED- 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
RANOLAZI NE ELC TABLET, PROLONG ED- RELEASE 375MG	RANOLAZI NE ELC TABLET, PROLONG ED- 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
RANOLAZI NE ELC TABLET, PROLONG ED- RELEASE 500MG	RANOLAZI NE ELC TABLET, PROLONG ED- 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
ROSUVAST ATIN AUROBIND O TABLET, FILM COATED 40MG	ROSUVAST ATIN AUROBIND O 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)*
ROSUVAST ATIN AUROBIND O TABLET, FILM COATED 5MG	ROSUVAST ATIN AUROBIND O 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)* C.I.z C.I.z - SAFETY, EFFICACY,
ROSUVAST ATIN AUROBIND O TABLET, FILM COATED 10MG	ROSUVAST ATIN AUROBIND O TABLET, FILM COATED 10MG	2843/23T, 2844/23T, 2845/23T	AUROBINDO PHARMA (MALTA) LIMITED	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product 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)*
ROSUVAST ATIN AUROBIND O TABLET, FILM COATED 20MG	ROSUVAST ATIN AUROBIND O 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, manufacture responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
ROSUVAST ATIN AUROBIND O TABLET, FILM COATED 40MG	ROSUVAST ATIN AUROBIND O 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
ROSUVAST ATIN AUROBIND O TABLET, FILM COATED 5MG	ROSUVAST ATIN AUROBIND O 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
ROSUVAST ATIN AUROBIND O TABLET, FILM COATED 10MG	ROSUVAST ATIN AUROBIND O 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
ROSUVAST ATIN AUROBIND O TABLET, FILM	ROSUVAST ATIN AUROBIND O 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	COATED			
20MG MECOLZIN	20MG MECOLZIN			C.I.z C.I.z - SAFETY, EFFICACY,
e Supposit Ory	E SUPPOSIT ORY		FAES FARMA	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other
500MG	500MG	9621/21T	SA	
MECOLZIN E SUPPOSIT ORY 1000MG	MECOLZIN E SUPPOSIT ORY 1000MG	9622/21T	FAES FARMA SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
1000110			JOHNSON &	
NIZORAL CREAM 2%	NIZORAL CREAM 2%	2593/23T	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)*
NEPHROT ECT SOLUTION FOR INFUSION 10%	NEPHROT ECT 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
LAMOTRIX TABLET 25MG	LAMOTRIX TABLET 25MG	6748/23T	MEDOCHEMIE LTD	in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 PHARMACEU TICALS 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 PHARMACEU TICALS 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

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BICOL TABLET, FILM COATED 25MG	BICOL TABLET, FILM COATED 25MG	7082/23T	DELORBIS PHARMACEU TICALS 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 STRAWBE RRY SUGAR FREE LOZENGE	STREPSILS STRAWBE RRY 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 NUROFEN COLD & FLU	STREPSILS HONEY & LEMON LOZENGE NUROFEN COLD & FLU	22/22T 26/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA RECKITT BENCKISER HELLAS	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance,

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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
LENALIDO MIDE STADA CAPSULE, HARD 7.5MG	LENALIDO MIDE 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 ARZNEIMITTE L 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
LENALIDO MIDE STADA CAPSULE, HARD	LENALIDO MIDE STADA CAPSULE, HARD	5374/23T, 5375/23T, 5376/23T, 5375/23T, 5376/23T, 5377/23T, 5378/23T, 5379/23T, 5380/23T, 5381/23T, 5382/23T, 5383/23T,	STADA ARZNEIMITTE	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
2.5MG	2.5MG	5384/23T, 5385/23T	LAG	or B.III.1.b.4 B.III.1.b.4 - QUALITY
LENALIDO MIDE STADA CAPSULE, HARD 10MG	LENALIDO MIDE STADA CAPSULE, HARD 10MG	5338/23T, 5339/23T, 5340/23T, 5341/23T, 5342/23T, 5343/23T, 5344/23T, 5345/23T, 5346/23T, 5345/23T, 5348/23T, 5349/23T	STADA ARZNEIMITTE L AG	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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
LENALIDO MIDE STADA CAPSULE, HARD 20MG	LENALIDO MIDE 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 ARZNEIMITTE L 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

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				- Submission of a new 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
LENALIDO MIDE STADA CAPSULE, HARD 5MG	LENALIDO MIDE STADA CAPSULE, HARD 5MG	5362/23T, 5363/23T, 5364/23T, 5365/23T, 5366/23T, 5365/23T, 5366/23T, 5369/23T, 5368/23T, 5369/23T, 5370/23T, 5371/23T, 5372/23T, 5373/23T	STADA ARZNEIMITTE L 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
LENALIDO MIDE STADA CAPSULE, HARD 15MG	LENALIDO MIDE 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 ARZNEIMITTE L 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)

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				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
LENALIDO MIDE STADA CAPSULE, HARD 25MG	LENALIDO MIDE STADA CAPSULE, HARD 25MG	5302/23T, 5303/23T, 5304/23T, 5305/23T, 5306/23T, 5305/23T, 5306/23T, 5307/23T, 5308/23T, 5309/23T, 5310/23T, 5311/23T, 5312/23T, 5313/23T	STADA ARZNEIMITTE L 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
PROPOFO L MCT/LCT/F RESENIUS EMULSION FOR INJECTION / INFUSION 10MG/ML IN PRE- FILLED SYRINGE	PROPOFO L MCT/LCT/F RESENIUS 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.
PROPOFO L MCT/LCT/F RESENIUS EMULSION FOR INJECTION / INFUSION 20MG/ML IN PRE- FILLED SYRINGE	PROPOFO L MCT/LCT/F RESENIUS 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.
TARGINAC T TABLET, PROLONG ED- RELEASE 40/20MG	TARGINAC T TABLET, PROLONG ED- RELEASE 40/20MG	4973/23T	MUNDIPHARM A PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

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				Pharmacopoeial Certificate of Suitability
				to the relevant Ph. Eur. Monograph - Updated certificate from an already
				approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
TARGINAC	TARGINAC			material/reagent/intermediate used in the manufacturing process of the active
T TABLET,	T TABLET,			substance For an excipient - European
PROLONG	PROLONG		MUNDIPHARM	Pharmacopoeial Certificate of Suitability
ED-	ED-		A	to the relevant Ph. Eur. Monograph -
RELEASE	RELEASE	4070/00T	PHARMACEU	Updated certificate from an already
5/2.5MG	5/2.5MG	4972/23T	TICALS LTD	approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
TARGINAC	TARGINAC			material/reagent/intermediate used in the manufacturing process of the active
T TABLET,	T TABLET,			substance For an excipient - European
PROLONG	PROLONG		MUNDIPHARM	Pharmacopoeial Certificate of Suitability
ED-	ED-		A	to the relevant Ph. Eur. Monograph -
RELEASE	RELEASE		PHARMACEU	Updated certificate from an already
10/5MG	10/5MG	4975/23T	TICALS LTD	approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
TARGINAC	TARGINAC			material/reagent/intermediate used in the manufacturing process of the active
T TABLET,	T TABLET,			substance For an excipient - European
PROLONG	PROLONG		MUNDIPHARM	Pharmacopoeial Certificate of Suitability
ED-	ED-		A	to the relevant Ph. Eur. Monograph -
RELEASE	RELEASE	4074/22T	PHARMACEU	Updated certificate from an already
20/10MG	20/10MG	4974/23T	TICALS LTD	approved manufacturer 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
OCTAGAM	OCTAGAM			biological / immunological substance or
SOLUTION	SOLUTION			use of a different chemically derived
FOR INFUSION	FOR INFUSION	4509/23T, 4510/23T,	OCTAPHARM	substance in the manufacture of a biological/immunological substance,
50MG/ML	50MG/ML	4511/23T	A (IP) SPRL	which may have a significant impact on
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				the quality, safety and efficacy of the medicinal product and is not related to a protocol
BERINERT	BERINERT			•
1500	1500			
POWDER	POWDER			
AND	AND			B.II.d.2.a B.II.d.2.a - QUALITY
SOLVENT	SOLVENT			CHANGES - FINISHED PRODUCT -
FOR	FOR			Control of finished product - Change in
SOLUTION	SOLUTION			test procedure for the finished product -
FOR	FOR	5000/00T	CSL BEHRING	Minor changes to an approved test
INJECTION	INJECTION	5262/23T	GMBH	procedure
BERINERT 500	BERINERT 500			
POWDER	POWDER			
AND	AND			
SOLVENT	SOLVENT			
FOR	FOR			B.II.d.2.a B.II.d.2.a - QUALITY
SOLUTION	SOLUTION			CHANGES - FINISHED PRODUCT -
FOR	FOR			Control of finished product - Change in
INFUSION/I	INFUSION/I			test procedure for the finished product -
NJECTION	NJECTION		CSL BEHRING	Minor changes to an approved test
500IU	500IU	5263/23T	GMBH	procedure
BERINERT	BERINERT			
2000	2000			
POWDER	POWDER			
AND	AND			
SOLVENT	SOLVENT			B.II.d.2.a B.II.d.2.a - QUALITY
FOR	FOR			CHANGES - FINISHED PRODUCT -
SOLUTION	SOLUTION			Control of finished product - Change in
FOR	FOR			test procedure for the finished product -
INJECTION 2000IU	INJECTION 2000IU	5261/23T	CSL BEHRING GMBH	Minor changes to an approved test procedure
BERINERT	BERINERT	0201/201		procedure
3000	3000			
POWDER	POWDER			
AND	AND			
SOLVENT	SOLVENT			B.II.d.2.a B.II.d.2.a - QUALITY
FOR	FOR			CHANGES - FINISHED PRODUCT -
SOLUTION	SOLUTION			Control of finished product - Change in
FOR	FOR			test procedure for the finished product -
INJECTION	INJECTION		CSL BEHRING	Minor changes to an approved test
3000IU	3000IU	5260/23T	GMBH	procedure
				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
				an active substance For a starting material/reagent/intermediate used in
CREON	CREON			the manufacturing process of the active
20000	20000			substance For an excipient - European
GASTRO-	GASTRO-			Pharmacopoeial TSE Certificate of
RESISTAN	RESISTAN			suitability for an active
T	T			substance/starting material/reagent/
CAPSULE,	CAPSULE,		VIATRIS	intermediate/or excipient - Updated
HARD	HARD		HEALTHCARE	certificate from an already approved
20000U	20000U	5847/23T	LIMITED.	manufacturer
				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
CREON	CREON			of Ph. Eur. certificate of suitability: For
35000	35000			an active substance For a starting
GASTRO-	GASTRO-			material/reagent/intermediate used in
RESISTAN T	RESISTAN T			the manufacturing process of the active
CAPSULE,	CAPSULE,		VIATRIS	substance For an excipient - European Pharmacopoeial TSE Certificate of
HARD	HARD		HEALTHCARE	suitability for an active
35000U	35000U	5846/23T	LIMITED.	substance/starting material/reagent/
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				intermediate/or excipient - Updated certificate from an already approved
TICOVAC JUNIOR SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 0.25ML/DO SE	TICOVAC JUNIOR SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 0.25ML/DO SE	5724/23T, 5725/23T	PFIZER HELLAS AE	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 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 SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 0.5ML/DOS E	TICOVAC SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 0.5ML/DOS E	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)
LENALIDO MIDE STADA CAPSULE, HARD 25MG	LENALIDO MIDE STADA CAPSULE, HARD 25MG	5277/23T	STADA ARZNEIMITTE L 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 SUSPENSI ON 250MG/5ML	REMEDOL 6+ ORAL SUSPENSI ON 250MG/5ML	3928/23T, 3929/23T, 3930/23T, 3931/23T, 3932/23T 3938/23T, 3939/23T,	REMEDICA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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 B.III.1.a.2 B.III.1.a.2 - QUALITY
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.

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ORY 125MG	ORY 125MG			Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
1251016	1251016			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
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new 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
REMEDOL	REMEDOL			the specification parameters and/or
SUPPOSIT	SUPPOSIT	3933/23T, 3934/23T,		limits of an active substance, starting
ORY	ORY	3935/23T, 3936/23T,	REMEDICA	material / intermediate / reagent used in
250MG	250MG	3937/23T	LTD	the manufacturing process of the
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermedia
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
REMEDOL	REMEDOL			material/reagent/intermedia
SUPPOSIT	SUPPOSIT	3943/23T, 3944/23T,		B.III.2.a.1 B.III.2.a.1 - QUALITY
ORY	ORY	3945/23T, 3946/23T,	REMEDICA	CHANGES - CEP/TSE/MONOGRAPHS
500MG	500MG	3947/23T	LTD	- Change to comply with Ph. Eur. or with

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				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 SUSPENSI ON 120MG/5ML	REMEDOL ORAL SUSPENSI ON 120MG/5ML	4104/23T, 4105/23T, 4106/23T, 4107/23T, 4108/23T	REMEDICA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new 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
PSOKADR ON PROLONG ED RELEASE SUSPENSI ON FOR INJECTION IN PREFILLED SYRINGE 75MG	PSOKADR ON PROLONG ED RELEASE SUSPENSI ON FOR INJECTION IN PREFILLED SYRINGE 75MG	6562/22T	PHARMATHE N 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)
PSOKADR ON PROLONG ED RELEASE SUSPENSI ON FOR INJECTION IN PREFILLED	PSOKADR ON PROLONG ED RELEASE SUSPENSI ON FOR INJECTION IN PREFILLED	6565/22T	PHARMATHE N 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)

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SYRINGE	SYRINGE			
150MG PSOKADR	150MG PSOKADR		+	
ON	ON			
PROLONG	PROLONG			
ED	ED			
RELEASE	RELEASE			
SUSPENSI	SUSPENSI			
				B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
INJECTION IN	INJECTION			CHANGES - FINISHED PRODUCT -
PREFILLED	PREFILLED			Stability - Change in the shelf-life or
SYRINGE	SYRINGE			storage conditions of the finished
100MG	100MG			product - Extension of the shelf life of
AND	AND	050 //00 T	PHARMATHE	the finished product - As packaged for
150MG	150MG	6564/22T	N S.A.	sale (supported by real time data)
PSOKADR ON	PSOKADR ON			
PROLONG	PROLONG			
ED	ED			
RELEASE	RELEASE			
SUSPENSI	SUSPENSI			B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
ON FOR	ON FOR			CHANGES - FINISHED PRODUCT -
				Stability - Change in the shelf-life or
IN PREFILLED	IN PREFILLED			storage conditions of the finished product - Extension of the shelf life of
SYRINGE	SYRINGE		PHARMATHE	the finished product - As packaged for
25MG	25MG	6563/22T	N S.A.	sale (supported by real time data)
PSOKADR	PSOKADR			
ON	ON			
PROLONG	PROLONG			
ED RELEASE	ED RELEASE			
SUSPENSI	SUSPENSI			B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
ON FOR	ON FOR			CHANGES - FINISHED PRODUCT -
INJECTION	INJECTION			Stability - Change in the shelf-life or
IN	IN			storage conditions of the finished
PREFILLED	PREFILLED			product - Extension of the shelf life of
SYRINGE	SYRINGE	6566/22T	PHARMATHE	the finished product - As packaged for
50MG PSOKADR	50MG PSOKADR	0300/221	N S.A.	sale (supported by real time data)
ON	ON			
PROLONG	PROLONG			
ED	ED			
RELEASE	RELEASE			
SUSPENSI	SUSPENSI			B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
ON FOR	ON FOR			CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or
IN	INJECTION			Stability - Change in the shelf-life or storage conditions of the finished
PREFILLED	PREFILLED			product - Extension of the shelf life of
SYRINGE	SYRINGE		PHARMATHE	the finished product - As packaged for
100MG	100MG	6561/22T	N S.A.	sale (supported by real time data)
				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
SYNTOCLA V TABLET,	SYNTOCLA V TABLET,			CHANGES - FINISHED PRODUCT - Control of finished product - Change in
FILM	FILM			test procedure for the finished product -
COATED	COATED		CODAL	Other changes to a test procedure
625MG	625MG	6378/23T, 6379/23T	SYNTO LTD	(including replacement or addition)
				B.II.d.1.c B.II.d.1.c - QUALITY
SYNTOCLA	SYNTOCLA			CHANGES - FINISHED PRODUCT -
V TABLET, FILM	V TABLET, FILM	6380/23T, 6381/23T	CODAL SYNTO LTD	Control of finished product - Change in the specification parameters and/or
		0300/231,0301/231	SINICLID	and specification parameters and/or

COATED	COATED			limits of the finished product - Addition
375MG	375MG			of a new specification parameter to the
				specification with its corresponding test
				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.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in the manufacturing process of the active
				substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
REMEDOL	REMEDOL			to the relevant Ph. Eur. Monograph -
TABLET	TABLET		REMEDICA	Updated certificate from an already
500MG	500MG	6485/23T	LTD	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermediate used in
REMEDOL	REMEDOL			the manufacturing process of the active
FC	FC			substance For an excipient - European
TABLET,	TABLET,			Pharmacopoeial Certificate of Suitability
FILM	FILM			to the relevant Ph. Eur. Monograph -
COATED	COATED		REMEDICA	Updated certificate from an already
500MG	500MG	6486/23T	LTD	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
PARACETA	PARACETA			substance For an excipient - European
MOL-	MOL-			Pharmacopoeial Certificate of Suitability
REMEDICA	REMEDICA			to the relevant Ph. Eur. Monograph -
TABLET	TABLET	C407/00T	REMEDICA	Updated certificate from an already
500MG GAVISCON	500MG	6487/23T	LTD	approved manufacturer
DOUBLE	GAVISCON DOUBLE		RECKITT	B.I.c.1.a B.I.c.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE -
ACTION	ACTION		BENCKISER	Container closure system - Change in
TABLET,	TABLET,		HELLAS	immediate packaging of the active
CHEWABL	CHEWABL		HEALTHCARE	substance - Qualitative and/or
E	E	4984/23T	SA	quantitative composition
GLATIRAM	GLATIRAM			
ER/MYLAN	ER/MYLAN			
SOLUTION	SOLUTION			
FOR	FOR			
INJECTION IN	INJECTION IN			A.1 A.1 - ADMINISTRATIVE
	IN PREFILLED		MYLAN	CHANGES - Change in the name
SYRINGE	SYRINGE		IRELAND	and/or address of the marketing
40MG/ML	40MG/ML	5086/23T	LIMITED	authorisation holder
ROPIVACAI	ROPIVACAI			B.II.b.5.c B.II.b.5.c - QUALITY
NE KABI	NE KABI			CHANGES - FINISHED PRODUCT -
SOLUTION	SOLUTION			Manufacture - Change to in-process
SOLUTION		1		tests or limits applied during the
FOR	FOR		FRESENIUS	tests or limits applied during the
	FOR INJECTION 2MG/ML	5044/23T, 5045/23T	KABI HELLAS	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
ROPIVACAI NE KABI SOLUTION FOR INFUSION 2MG/ML	ROPIVACAI NE 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
ROPIVACAI NE KABI SOLUTION FOR INJECTION 5MG/ML	ROPIVACAI NE 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
ROPIVACAI NE KABI SOLUTION FOR INJECTION 7.5MG/ML	ROPIVACAI NE KABI SOLUTION FOR INJECTION 7.5MG/ML	5040/231, 5041/231 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 B.II.b.5.c B.II.b.5.c - QUALITY
ROPIVACAI NE KABI SOLUTION FOR	ROPIVACAI NE KABI SOLUTION FOR	5036/23T, 5037/23T	FRESENIUS KABI HELLAS A.E.	B.II.D.S.C B.II.D.S.C - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the

INJECTION	INJECTION			manufacture of the finished product -
10MG/ML	10MG/ML			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
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in the manufacturing process of 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 -
AZITHRAN	AZITHRAN			Control of active substance - Change in test procedure for active substance or
TABLET, FILM	TABLET, FILM		SAPIENS	starting material/reagent/intermediate used in the manufacturing process of
COATED 250MG	COATED 250MG	775/23T, 776/23T	PHARMACEU TICALS LTD	the active substance - Minor changes to an approved test procedure
CHORIOM	CHORIOM	110,201,110,201		
POWDER	POWDER			
AND SOLVENT	AND SOLVENT			B.II.c.3.z B.II.c.3.z - QUALITY CHANGES - FINISHED PRODUCT -
FOR SOLUTION	FOR SOLUTION			Control of excipients - Change in source of an excipient or reagent with TSE risk
FOR	FOR		IBSA FARMACEUTI	- B.II.c.3.z Change in source of excipient unlikely to present any risk of
5000IU	5000IU	4293/23T	CI ITALIA SRL	TSE contamination
				B.II.e.6.b B.II.e.6.b - QUALITY CHANGES - FINISHED PRODUCT -
PENEMER POWDER	PENEMER POWDER			Container closure system - Change in any part of the (primary) packaging
FOR	FOR			material not in contact with the finished
SOLUTION FOR	SOLUTION FOR			product formulation (such as colour of flip-off caps, colour code rings on
INJECTION /INFUSION	INJECTION /INFUSION		CODAL- SYNTO	ampoules, change of needle shield (different plastic used)) - Change that
1G/VIAL	1G/VIAL	6401/23T	LIMITED	does not affect the product information B.II.e.6.b B.II.e.6.b - QUALITY
PENEMER POWDER	PENEMER POWDER			CHANGES - FINISHED PRODUCT -
FOR	FOR			Container closure system - Change in any part of the (primary) packaging
SOLUTION FOR	SOLUTION FOR			material not in contact with the finished product formulation (such as colour of
INJECTION /INFUSION	INJECTION /INFUSION		CODAL-	flip-off caps, colour code rings on ampoules, change of needle shield
500MG/VIA	500MG/VIA	6400/22T	SYNTO	(different plastic used)) - Change that
L	L	6400/23T		does not affect the product information B.III.1.a.3 B.III.1.a.3 - QUALITY
LAMOTRIX	LAMOTRIX			CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
TABLET	TABLET 50MG	5242/23T, 5243/23T,	MEDOCHEMIE LTD	Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For
50MG	SUNG	5244/23T		

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				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	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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	B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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)*
				B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate 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
LAMOTRIX				place, or supplier of a starting material,
TABLET 100MG	TABLET 100MG	5239/23T, 5240/23T, 5241/23T	MEDOCHEMIE LTD	reagent or excipient (when mentioned in the dossier)*
1001010	1001010	5241/251		C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar
				medicinal products following assessment of the same change for the
				reference product - Implementation of
VACONTIL	VACONTIL			change(s) for which no new additional
CAPSULE,	CAPSULE,	0005/00T	MEDOCHEMIE	data is required to be submitted by the
HARD 2MG	HARD 2MG	6225/23T	LTD	MAH C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar
				medicinal products following
				assessment of the same change for the reference product - Implementation of
VACONTIL	VACONTIL			change(s) for which no new additional
TABLET	TABLET		MEDOCHEMIE	data is required to be submitted by the
2MG	2MG	6218/23T	LTD	
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
			JOHNSON &	an active substance For a starting material/reagent/intermediate used in
			JOHNSON	the manufacturing process of the active
DAKTARIN	DAKTARIN		HELLAS	substance For an excipient - European
POWDER		5647/22T		Pharmacopoeial Certificate of Suitability
2% W/W	2% W/W	5647/23T	AE	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
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
DAKTODO R CREAM (2% + 1%) w/w	DAKTODO R CREAM (2% + 1%) w/w	5651/23T	JOHNSON & JOHNSON HELLAS CONSUMER AE	- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 HYDROCH LORIDE NORIDEM SOLUTION FOR INJECTION 10 MG/ML	LIDOCAINE HYDROCH LORIDE NORIDEM SOLUTION FOR INJECTION 10 MG/ML	6620/23T	NORIDEM ENTERPRISE S LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 HYDROCH LORIDE NORIDEM SOLUTION FOR INJECTION 20 MG/ML	LIDOCAINE HYDROCH LORIDE NORIDEM SOLUTION FOR INJECTION 20 MG/ML	6619/23T	NORIDEM ENTERPRISE S LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 DEUTSCHLAN D 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

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				test procedure for the finished product - Minor changes to an approved test procedure
REPRAT TABLET, GASTRO- RESISTAN T 40MG	REPRAT TABLET, GASTRO- RESISTAN T 40MG	7050/23T	DELORBIS PHARMACEU TICALS 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- RESISTAN T 20MG	REPRAT TABLET, GASTRO- RESISTAN T 20MG	7051/23T	DELORBIS PHARMACEU TICALS 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 GLUCONA TE TABLET, FILM COATED 300MG	FERROUS GLUCONA TE 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 GLUCONA TE TABLET, FILM COATED 300MG	FERROUS GLUCONA TE TABLET, FILM COATED 300MG	6446/23T	REMEDICA	A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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 INHALATIO N 200MCG/D OSE	FRENOLYN POWDER FOR INHALATIO N 200MCG/D OSE	6277/23T, 6278/23T	MEDOCHEMIE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 INHALATIO N 400MCG/D OSE	FRENOLYN POWDER FOR INHALATIO N 400MCG/D OSE	6275/23T, 6276/23T	MEDOCHEMIE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 ARZNEIMITTE L 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

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				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 manufacture - Replacement or addition of a manufacturing site for part or all of the 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 manufacture - Replacement or addition of a manufacture - Replacement or addition
				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 -

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HEXARHIN	HEXARHIN		JOHNSON &	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 B.II.e.4.c B.II.e.4.c - QUALITY CHANGES - FINISHED PRODUCT -
AL NASAL SPRAY, SOLUTION 1MG/ML	AL NASAL SPRAY, SOLUTION 1MG/ML	3550/23T	JOHNSON JOHNSON HELLAS CONSUMER AE	Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products
BETNOVAT E SCALP APPLICATI ON CUTANEO US SOLUTION 0.1% W/W	BETNOVAT E SCALP APPLICATI ON CUTANEO US SOLUTION 0.1% W/W	5938/23T	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
LOSARTAN AUROBIND O TABLET, FILM COATED 50MG	LOSARTAN AUROBIND O 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
PAROXETI NE AUROBIND O TABLET, FILM COATED 30MG	PAROXETI NE AUROBIND O 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
PAROXETI NE AUROBIND O TABLET, FILM COATED 20MG	PAROXETI NE AUROBIND O 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

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				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
AZACITIDI NE PHARMAS CIENCE POWDER FOR SUSPENSI ON FOR INJECTION 25MG/ML	AZACITIDI NE PHARMAS CIENCE POWDER FOR SUSPENSI ON FOR INJECTION 25MG/ML	5699/23T	PHARMASCIE NCE INTERNATION AL 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, SUSPENSI ON	ISOPTO- MAXITROL EYE DROPS, SUSPENSI ON	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
RIVAROXA BAN/SAND OZ TABLET, FILM COATED 10MG	RIVAROXA BAN/SAND OZ TABLET, FILM COATED 10MG	3919/23T	SANDOZ PHARMACEU TICALS 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- RESISTAN T 40MG	REPRAT TABLET, GASTRO- RESISTAN T 40MG	6925/23T	DELORBIS 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)
REPRAT TABLET, GASTRO- RESISTAN T 20MG	REPRAT TABLET, GASTRO- RESISTAN T 20MG	6926/23T	DELORBIS 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)
MYELOMID E CAPSULE, HARD 25MG	MYELOMID E 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
MYELOMID E CAPSULE, HARD 5MG	MYELOMID E 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
MYELOMID E CAPSULE, HARD 15MG	MYELOMID E 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
MYELOMID E CAPSULE, HARD 10MG	MYELOMID E 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
DERMOVA TE CREAM 0.05% W/W	DERMOVA TE CREAM 0.05% W/W	6874/23T	GLAXOSMITH KLINE (IRELAND) LIMITED	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
SMOFKABI VEN EXTRA NITROGEN EMULSION FOR INFUSION	SMOFKABI VEN 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) B.II.f.1.b.3 B.II.f.1.b.3 - QUALITY
SMOFKABI VEN EXTRA NITROGEN ELECTROL YTE FREE EMULSION FOR INFUSION	SMOFKABI VEN EXTRA NITROGEN ELECTROL YTE FREE EMULSION FOR INFUSION	3538/23T, 3539/23T	FRESENIUS KABI HELLAS SINGLE MEMBER S.A.	B.II.T.1.D.3 B.II.T.1.D.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 SUSTAINE D RELEASE TABLETS 5MG	XATRAL SUSTAINE D 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, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of 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

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XATRAL OD TABLET, PROLONG ED- RELEASE 10MG	XATRAL OD TABLET, PROLONG ED- 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, starting material / intermediate / B.I.b.2.a B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of 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
PARCOTE N COLD & FLU TABLET, FILM COATED 500MG/30M G/15MG/60 MG	PARCOTE N COLD & FLU TABLET, FILM COATED 500MG/30M G/15MG/60 MG	5899/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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

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				1901/2006 - Implementation of wording agreed by the competent authority
				B.II.b.4.a B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT -
MOXICLAV	MOXICLAV			Manufacture - Change in the batch size
TABLET,	TABLET,			(including batch size ranges) of the
FILM	FILM			finished product - Up to 10-fold
COATED 1G	COATED 1G	6735/23T	MEDOCHEMIE LTD	compared to the originally approved batch size
		0100/201		C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products intended to implement the outcome of a
CEFUROXI	CEFUROXI			procedure concerning PSUR or PASS,
ME-SYNTO	ME-SYNTO			or the outcome of the assessment done
TABLET,	TABLET,		00004	by the competent authority under
FILM COATED	FILM COATED		CODAL- SYNTO	Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
250MG	250MG	6853/23T	LIMITED	agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package Leaflet of human medicinal products
				intended to implement the outcome of a
CEFUROXI	CEFUROXI			procedure concerning PSUR or PASS,
ME-SYNTO	ME-SYNTO			or the outcome of the assessment done
TABLET, FILM	TABLET, FILM		CODAL-	by the competent authority under Articles 45 or 46 of Regulation
COATED	COATED		SYNTO	1901/2006 - Implementation of wording
500MG CEFUROXI	500MG CEFUROXI	6852/23T	LIMITED	agreed by the competent authority B.II.d.2.a B.II.d.2.a - QUALITY
ME-SYNTO	ME-SYNTO			CHANGES - FINISHED PRODUCT -
TABLET,	TABLET,			Control of finished product - Change in
FILM COATED	FILM COATED		CODAL- SYNTO	test procedure for the finished product - Minor changes to an approved test
250MG	250MG	4981/23T, 4982/23T	LIMITED	procedure
CEFUROXI	CEFUROXI	,		B.II.d.2.a B.II.d.2.a - QUALITY
ME-SYNTO	ME-SYNTO			CHANGES - FINISHED PRODUCT -
TABLET, FILM	TABLET, FILM		CODAL-	Control of finished product - Change in test procedure for the finished product -
COATED	COATED		SYNTO	Minor changes to an approved test
500MG	500MG	4979/23T, 4980/23T	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
				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
NAROX TABLET,	NAROX TABLET,	6679/23T, 6680/23T,		(where specified in the technical doss B.I.b.1.d B.I.b.1.d - QUALITY
FILM	FILM	6681/23T, 6682/23T,	DELORBIS	CHANGES - ACTIVE SUBSTANCE -
COATED	COATED	6683/23T, 6684/23T,	PHARMACEU	Control of active substance - Change in
90MG	90MG	6685/23T	TICALS LTD	the specification parameters and/or

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				limits of an active substance, starting material / intermediate / reagent used in
				the manufacturing process of the active
				substance - Deletion of a non-significant
				specification parameter (e.g. dele
				B.I.b.2.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
NAROX	NAROX			limits of an active substance, starting
TABLET,	TABLET,	6693/23T, 6694/23T,		material / intermediate / reagent used in
FILM	FILM	6695/23T, 6696/23T,	DELORBIS	the manufacturing process of the active
COATED 30MG	COATED 30MG	6697/23T, 6698/23T, 6699/23T	PHARMACEU TICALS LTD	substance - Deletion of a non-significant specification parameter (e.g. dele
301010	301010	0099/231	TICALS 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
NAROX	NAROX			the specification parameters and/or limits of an active substance, starting
TABLET,	TABLET.	6686/23T, 6687/23T,		material / intermediate / reagent used in
FILM	FILM	6688/23T, 6689/23T,	DELORBIS	the manufacturing process of the active
COATED	COATED	6690/23T, 6691/23T,	PHARMACEU	substance - Deletion of a non-significant
60MG	60MG	6692/23T	TICALS LTD	specification parameter (e.g. dele
				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
NAROX	NAROX			A.4 A.4 - ADMINISTRATIVE CHANGES
TABLET,	TABLET,	6672/23T, 6673/23T,		- Change in the name and/or address
FILM	FILM	6674/23T, 6675/23T,	DELORBIS	of: a manufacturer (including where
COATED 120MG	COATED 120MG	6676/23T, 6677/23T, 6678/23T	PHARMACEU TICALS LTD	relevant quality control testing sites); or an ASMF holder; or a supplier of the
	1201010	0010/201		an Aomin 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 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
NEURONTI	NEURONTI			the manufacturing process of the active substance For an excipient - European
Ν	Ν			Pharmacopoeial Certificate of Suitability
CAPSULE,	CAPSULE,			to the relevant Ph. Eur. Monograph -
HARD 400MG	HARD 400MG	5869/23T, 5870/23T	UPJOHN HELLAS LTD	Updated certificate from an already approved manufacturer
				B.III.1.a.4 B.III.1.a.4 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in the manufacturing process of the active
				substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
				to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple
				certificates exist per material)
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in the manufacturing process of the active
NEURONTI	NEURONTI			substance For an excipient - European
N CAPSULE,	N CAPSULE,			Pharmacopoeial Certificate of Suitability
HARD	HARD		UPJOHN	to the relevant Ph. Eur. Monograph - Updated certificate from an already
300MG	300MG	5871/23T, 5872/23T	HELLAS LTD	approved manufacturer
CREON	CREON			B.III.1.b.3 B.III.1.b.3 - QUALITY
10000 CAPSULE,	10000 CAPSULE,		VIATRIS	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
HARD	HARD		HEALTHCARE	Eur. Certificate of suitability or deletion
150MG	150MG	6819/23T	LIMITED.	of Ph. Eur. certificate of suitability: For

				an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active
				substance For an excipient - European Pharmacopoeial TSE Certificate of
				suitability for an active substance/starting material/reagent/
				intermediate/or excipient - Updated certificate from an already approved manufacturer
				B.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
XYZAL	XYZAL			substance, where no Ph. Eur. Certificate of Suitability is part of the approved
ORAL SOLUTION	ORAL SOLUTION		UCB PHARMA	dossier - Introduction of a manufacturer of the active substance supported by an
0.5MG/ML	0.5MG/ML	1776/23T	SA	ASMF C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar medicinal products following
AMESOL TABLET,	AMESOL TABLET,			assessment of the same change for the reference product - Implementation of
FILM COATED	FILM COATED	6660/00T	MEDOCHEMIE	change(s) for which no new additional data is required to be submitted by the
250MG	250MG	6662/23T	LTD	MAH C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
AMESOL	AMESOL			Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the
TABLET, FILM	TABLET, FILM			reference product - Implementation of change(s) for which no new additional
COATED 500MG	COATED 500MG	6661/23T	MEDOCHEMIE LTD	data is required to be submitted by the MAH
				A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
ZADITEN	ZADITEN			and/or address of a manufacturer/importer of the finished product (including batch release or
EYE DROPS,	EYE DROPS,			quality control testing sites) - The activities for which the
SOLUTION 0.25MG/ML	SOLUTION 0.25MG/ML	5168/23T	LABORATOIR ES THEA	manufacturer/importer is responsible do not include batch release
				A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
OCULOTE	OCULOTE			and/or address of a manufacturer/importer of the finished product (including batch release or
CT FLUID SINE EYE	CT FLUID SINE EYE			quality control testing sites) - The activities for which the
DROPS 5G/100ML	DROPS 5G/100ML	5167/23T	LABORATOIR ES THEA	manufacturer/importer is responsible do not include batch release
VOLTAREN OPHTHA	VOLTAREN OPHTHA	5166/23T	LABORATOIR ES 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
ROSUVAST ATIN/MYLA N TABLET, FILM COATED 10MG	ROSUVAST ATIN/MYLA N 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
ROSUVAST ATIN/MYLA N TABLET, FILM COATED 20MG	ROSUVAST ATIN/MYLA N 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
ROSUVAST ATIN/MYLA N TABLET, FILM COATED 5MG	ROSUVAST ATIN/MYLA N 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
ROSUVAST ATIN/MYLA N TABLET, FILM COATED 40MG TRIPLIXAM TABLET, FILM COATED	ROSUVAST ATIN/MYLA N TABLET, FILM COATED 40MG TRIPLIXAM TABLET, FILM COATED	5889/23T 4096/23T	MYLAN IRELAND LIMITED LES LABORATOIR ES 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 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/1.25M G/10MG	5MG/1.25M G/10MG			Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently
TRIPLIXAM TABLET, FILM COATED 10MG/2.5M G/10MG	TRIPLIXAM TABLET, FILM COATED 10MG/2.5M G/10MG	4098/23T	LES LABORATOIR ES SERVIER	approved pack sizes 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/2.5M G/5MG	TRIPLIXAM TABLET, FILM COATED 10MG/2.5M G/5MG	4097/23T	LES LABORATOIR ES 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/1.25M G/5MG	TRIPLIXAM TABLET, FILM COATED 5MG/1.25M G/5MG	4095/23T	LES LABORATOIR ES 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
CARBOPLA TIN ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 10MG/ML	CARBOPLA TIN ACCORD CONCENT RATE 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	MUNDIPHARM A PHARMACEU TICALS 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, 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, 4832/22T, 4835/22T, 4836/22T, 4835/22T, 4836/22T, 4837/22T, 4838/22T, 4839/22T, 4840/22T	MUNDIPHARM A PHARMACEU TICALS 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, 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
TENOVIRA L TABLET, FILM COATED 123MG	TENOVIRA L TABLET, FILM COATED 123MG	4478/23T	REMEDICA	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)
TENOVIRA L TABLET, FILM COATED 163MG TENOVIRA	TENOVIRA L TABLET, FILM COATED 163MG TENOVIRA	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) C.I.11.z C.I.11.z - SAFETY,
L TABLET, FILM	L TABLET, FILM	4475/23T	REMEDICA LTD	EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND

001755	004755	[
COATED	COATED			
245MG	245MG			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
	l			wording + template change)
				C.I.11.z C.I.11.z - SAFETY,
				EFFICACY, PHARMACOVIGILANCE
				CHANGES - HUMAN AND
				VETERINARY MEDICINAL
TENON	TENIO (15.4			PRODUCTS - Introduction of, or
TENOVIRA	TENOVIRA			change(s) to, the obligations and
L TABLET,	L TABLET,			conditions of a marketing authorisation,
FILM COATED	FILM COATED		REMEDICA	including the risk management plan -
	204MG	4476/22T	-	Other RMP changes (e.g. agreed
204MG	2041VIG	4476/23T	LTD	wording + template change)
				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
	1			B.II.e.2.b B.II.e.2.b - QUALITY CHANGES - FINISHED PRODUCT -
ROSUVAST	ROSUVAST			Changes - Finished PRODUCT - Container closure system - Change in
ATIN	ATIN			the specification parameters and/or
ACCORD	ACCORD			limits of the immediate packaging of the
TABLET,	TABLET,			finished product - Addition of a new
FILM	FILM		ACCORD	specification parameter to the
COATED	COATED		HEALTHCARE	specification with its corresponding test
10MG	10MG	4460/23T, 4461/23T	S.L.U	method
		++00/201, ++01/201	0.2.0	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 -
ROSUVAST	ROSUVAST			Container closure system - Change in
ATIN	ATIN			the specification parameters and/or
ACCORD	ACCORD			limits of the immediate packaging of the
TABLET,	TABLET,			finished product - Addition of a new
FILM	FILM		ACCORD	specification parameter to the
COATED	COATED		HEALTHCARE	specification with its corresponding test
20MG	20MG	4458/23T, 4459/23T	S.L.U	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
	1			packaging of the finished product -
				Minor changes to an approved test
	1			procedure
				B.II.e.2.b B.II.e.2.b - QUALITY
				CHANGES - FINISHED PRODUCT -
ROSUVAST	ROSUVAST			Container closure system - Change in
ATIN	ATIN			the specification parameters and/or
ACCORD	ACCORD			limits of the immediate packaging of the
TABLET,	TABLET,			finished product - Addition of a new
FILM	FILM		ACCORD	specification parameter to the
COATED	COATED		HEALTHCARE	specification with its corresponding test
5MG	5MG	4462/23T, 4463/23T	S.L.U	method
ROSUVAST	ROSUVAST			B.II.e.3.a B.II.e.3.a - QUALITY
ATIN	ATIN			CHANGES - FINISHED PRODUCT -
ACCORD	ACCORD		ACCORD	Container closure system - Change in
TABLET,	TABLET,	4450/00T 4457/00T	HEALTHCARE	test procedure for the immediate
FILM	FILM	4456/23T, 4457/23T	S.L.U	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	XEOMIN POWDER FOR SOLUTION FOR INJECTION 50 UNITS XEOMIN	5407/23T, 5408/23T	MERZ PHARMACEU TICALS 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
POWDER FOR SOLUTION FOR INJECTION 100 UNITS	POWDER FOR SOLUTION FOR INJECTION 100 UNITS	5405/23T, 5406/23T	MERZ PHARMACEU TICALS 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 PHARMACEU TICALS 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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

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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	FUGENTIN POWDER FOR ORAL SUSPENSI		ELPEN PHARMACEU	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 -
ON 1G	ON 1G	887/23T, 888/23T	TICAL CO INC	HUMAN AND VETERINARY

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				MEDICINAL PRODUCTS - Other variation
SYNTOCIN ON CONCENT RATE FOR SOLUTION FOR INFUSION AND INJECTION 10 IU/ML	SYNTOCIN ON CONCENT RATE 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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
MEDOSTA TIN TABLET 20MG	MEDOSTA TIN TABLET 20MG	3082/23T	MEDOCHEMIE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product 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
MEDOSTA TIN TABLET 40MG	MEDOSTA TIN TABLET 40MG	3081/23T	MEDOCHEMIE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product 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/1000 MG	VIDELMET TABLET, FILM COATED 50MG/1000 MG	6789/23T	DELORBIS PHARMACEU TICALS 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

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VIDELMET TABLET, FILM COATED 50MG/850M G	VIDELMET TABLET, FILM COATED 50MG/850M G	6790/23T	DELORBIS PHARMACEU TICALS 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	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, PROLONG ED- RELEASE 60MG NYSTALOC	MONOREM R TABLET, PROLONG ED- RELEASE 60MG NYSTALOC	6481/23T, 6482/23T, 6483/23T, 6484/23T	REMEDICA LTD A.D.L.	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: For an active substance For a starting material/reagent/intermedia B.III.1.a.2 B.III.1.a.2 - QUALITY
AL CREAM (100000U.I/ 1MG/11.5M G)/G	AL CREAM (100000U.I/ 1MG/11.5M G)/G	2900/23T, 2901/23T	PHARMACEU TICAL PRODUCTSLI NE LIMITED	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For

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				an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 A.5.b A.5.b - ADMINISTRATIVE
AMLODIPIN ACCORD TABLET 5MG	AMLODIPIN ACCORD TABLET 5MG	5752/23T	ACCORD HEALTHCARE S.L.U	CHANGES - Change in the name and/or address of a manufacturer/importer of the 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 AUGMENTI	LAMISIL TABLET 125MG AUGMENTI	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 B.III.1.a.3 B.III.1.a.3 - QUALITY
N ES POWDER	N ES POWDER	2093/23T, 2094/23T	GLAXOSMITH KLINE	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

FOR ORAL SUSPENSI ON (600+42.9) MG/5ML PANTOPRA	FOR ORAL SUSPENSI ON (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
ZOLE ACCORD POWDER FOR SOLUTION FOR INJECTION 40MG/VIAL	ZOLE 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
SYNTOCLA V TABLET, FILM COATED 875/125MG	SYNTOCLA V 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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- RESISTAN T CAPSULE, HARD 20MG	PENRAZOL GASTRO- RESISTAN T CAPSULE, HARD 20MG	2949/23T, 2950/23T	ELPEN PHARMACEU TICAL 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
				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
LANSO	LANSO			CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test
GASTRO-	GASTRO-			period/storage period or storage
RESISTAN	RESISTAN			conditions of the active substance
T CAPSULE,	T CAPSULE,		IASIS PHARMACEU	where no Ph. Eur. Certificate of Suitability covering the retest period is
HARD	HARD		TICALS	part of the approved dossier - Re-test
30MG	30MG	6284/23T, 6285/23T	HELLAS SA	period/storage period - C.I.4 C.I.4 - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
PONSTAN	PONSTAN			HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
TABLET, FILM	TABLET, FILM			Characteristics, Labelling or Package
COATED	COATED		PFIZER	Leaflet due to new quality, preclinical,
500MG XEOMIN	500MG XEOMIN	3195/22T	HELLAS AE	clinical or pharmacovigilance data B.II.b.2.a B.II.b.2.a - QUALITY
POWDER	POWDER			CHANGES - FINISHED PRODUCT -
FOR	FOR			Manufacture - Change to importer,
FOR	FOR		MERZ	batch release arrangements and quality control testing of the finished product -
INJECTION	INJECTION		PHARMACEU	Replacement or addition of a site where
50 UNITS	50 UNITS	5402/23T	TICALS GMBH	batch control/testing takes place
XEOMIN POWDER	XEOMIN POWDER			B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT -
FOR	FOR			Manufacture - Change to importer,
SOLUTION FOR	SOLUTION FOR		MERZ	batch release arrangements and quality control testing of the finished product -
INJECTION	INJECTION			Replacement or addition of a site where
100 UNITS	100 UNITS	5401/23T	TICALS GMBH	batch control/testing takes place
XEOMIN POWDER	XEOMIN POWDER			B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT -
FOR	FOR			Manufacture - Change to importer,
SOLUTION	SOLUTION			batch release arrangements and quality
FOR INJECTION	FOR INJECTION		MERZ PHARMACEU	control testing of the finished product - Replacement or addition of a site where
200 UNITS	200 UNITS	5400/23T	TICALS GMBH	batch control/testing takes place
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
AKILEN TABLET,	AKILEN TABLET,			an active substance For a starting material/reagent/intermediate used in
FILM	FILM			the manufacturing process of the active
COATED		6326/23T 6227/22T	MEDOCHEMIE LTD	substance For an excipient - European
80MG	80MG	6326/23T, 6327/23T		Pharmacopoeial Certificate of Suitability

				to the relevant Ph. Eur. Monograph - Updated certificate from an already
				approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
AKILEN TABLET,	AKILEN TABLET,			substance For an excipient - European Pharmacopoeial Certificate of Suitability
FILM	FILM			to the relevant Ph. Eur. Monograph -
COATED	COATED		MEDOCHEMIE	Updated certificate from an already
40MG	40MG	6328/23T, 6329/23T	LTD	approved manufacturer B.II.a.3.b.6 B.II.a.3.b.6 - QUALITY
				CHANGES - FINISHED PRODUCT -
				Description and composition - Changes
JIVOLAR TABLET,	JIVOLAR TABLET,			in the composition (excipients) of the finished product - Other excipients -
FILM	FILM			Replacement of a single excipient with a
COATED	COATED			comparable excipient with the same
50MG/850M	50MG/850M	40.44/00T	MEDOCHEMIE	functional characteristics and at a
G	G	4241/23T	LTD	similar level B.II.a.3.b.6 B.II.a.3.b.6 - QUALITY
				CHANGES - FINISHED PRODUCT -
JIVOLAR	JIVOLAR			Description and composition - Changes in the composition (excipients) of the
TABLET,	TABLET,			finished product - Other excipients -
FILM	FILM			Replacement of a single excipient with a
COATED 50MG/1000	COATED 50MG/1000		MEDOCHEMIE	comparable excipient with the same functional characteristics and at a
MG	MG	4240/23T	LTD	similar level
AMPICILLI N/SULBAC	AMPICILLI			
TAM	N/SULBAC TAM			
APTAPHAR	APTAPHAR			
MA POWDER	MA POWDER			
FOR	FOR			
SOLUTION	SOLUTION			
FOR INJECTION	FOR INJECTION		APTA MEDICA	B.I.z B.I.z - QUALITY CHANGES -
/INFUSION	/INFUSION		INTERNACION	ACTIVE SUBSTANCE - Substantial
2G/1G	2G/1G	3294/23T	AL D.O.O.	updates to Mod. 3.2.S or the ASMF
AMPICILLI N/SULBAC	AMPICILLI N/SULBAC			
ТАМ	ТАМ			
APTAPHAR MA	APTAPHAR MA			
POWDER	POWDER			
FOR	FOR			
SOLUTION FOR	SOLUTION FOR			
INJECTION	INJECTION		APTA MEDICA	B.I.z B.I.z - QUALITY CHANGES -
/INFUSION	/INFUSION	2205/22T		ACTIVE SUBSTANCE - Substantial
1G/0.5G	1G/0.5G	3295/23T	AL D.O.O.	updates to Mod. 3.2.S or the ASMF 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
ERMYCIN TABLET,	ERMYCIN TABLET,			CHANGES - FINISHED PRODUCT - Description and composition - Changes
FILM	FILM			in the composition (excipients) of the
COATED	COATED	6230/23T, 6231/23T,	REMEDICA	finished product - Other changes
500MG	500MG	6232/23T	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
ERMYCIN TABLET, FILM COATED	ERMYCIN TABLET, FILM COATED	6227/23T, 6228/23T,	REMEDICA	in the composition (excipients) of the finished product - Other changes A.3 A.3 - ADMINISTRATIVE CHANGES - Change in name of the active
250MG	250MG	6229/23T	LTD	substance or of an excipient A.7 A.7 - ADMINISTRATIVE
ATALINE SYRUP	ATALINE SYRUP		MEDOCHEMIE	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the
1.5MG/5ML	1.5MG/5ML	6320/23T	LTD	dossier)* A.7 A.7 - ADMINISTRATIVE
ADRENALI NE INJECTION 1MG/ML	ADRENALI NE INJECTION 1MG/ML	6411/23T	NORIDEM ENTERPRISE S LTD	CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer 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, CHEWABL E 4MG	MONTOL TABLET, CHEWABL E 4MG	5820/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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, CHEWABL E 5MG	MONTOL TABLET, CHEWABL E 5MG	5819/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
				Updated certificate from an already
				approved manufacturer B.I.b.1.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
OCTISET	OCTISET			substance - Minor change in the
VAGINAL SOLUTION	VAGINAL SOLUTION	6093/23T, 6094/23T, 6095/23T	T.C.CHRISTO FOROU LTD.	manufacturing process of the active substance
		0000/201		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 -
OCTISET	OCTISET			Manufacture - Changes in the
CUTANEO	CUTANEO			manufacturing process of the active substance - Minor change in the
US	US	6096/23T, 6097/23T,	T.C.CHRISTO	manufacturing process of the active
SOLUTION MYOVIEW	SOLUTION MYOVIEW	6098/23T	FOROU LTD.	substance C.I.4 C.I.4 - SAFETY, EFFICACY,
KIT FOR	KIT FOR			PHARMACOVIGILANCE CHANGES -
RADIOPHA RMACEUTI	RADIOPHA RMACEUTI			HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
CAL	CAL		GE	in the Summary of Product
PREPARAT	PREPARAT		HEALTHCARE	Characteristics, Labelling or Package
ION 0.23MG	ION 0.23MG	4422/22T, 4423/22T	AS (NYDALEN)	Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
GEODON	GEODON	, .,		
POWDER AND	POWDER AND			
SOLVENT	SOLVENT			
FOR	FOR			
SOLUTION FOR	SOLUTION FOR			A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
INJECTION	INJECTION		UPJOHN	and/or address of the marketing
20MG/ML GEODON	20MG/ML GEODON	4302/23T	HELLAS LTD	authorisation holder A.1 A.1 - ADMINISTRATIVE
CAPSULE,	CAPSULE,			CHANGES - Change in the name
HARD	HARD	4004/007	UPJOHN	and/or address of the marketing
60MG GEODON	60MG GEODON	4304/23T	HELLAS LTD	authorisation holder A.1 A.1 - ADMINISTRATIVE
CAPSULE,	CAPSULE,			CHANGES - Change in the name
HARD 80MG	HARD 80MG	4303/23T	UPJOHN HELLAS LTD	and/or address of the marketing authorisation holder
EPANUTIN	EPANUTIN	1000/201		A.1 A.1 - ADMINISTRATIVE
CAPSULE,	CAPSULE,			CHANGES - Change in the name
HARD 100MG	HARD 100MG	4307/23T	VIATRIS HELLAS LTD	and/or address of the marketing authorisation holder
CARDURA	CARDURA			
TABLET 2MG	TABLET 2MG	4301/23T	UPJOHN HELLAS LTD	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
21010		7001/201		

	1		1	
				and/or address of the marketing authorisation holder
				A.1 A.1 - ADMINISTRATIVE
CARDURA	CARDURA			CHANGES - Change in the name
TABLET	TABLET	1000/00 T	UPJOHN	and/or address of the marketing
4MG GEODON	4MG GEODON	4300/23T	HELLAS LTD	authorisation holder A.1 A.1 - ADMINISTRATIVE
CAPSULE,	CAPSULE,			CHANGES - Change in the name
HARD	HARD		UPJOHN	and/or address of the marketing
40MG	40MG	4305/23T	HELLAS LTD	authorisation holder
GEODON	GEODON CAPSULE,			A.1 A.1 - ADMINISTRATIVE
CAPSULE, HARD	HARD		UPJOHN	CHANGES - Change in the name and/or address of the marketing
20MG	20MG	4306/23T	HELLAS LTD	authorisation holder
CASPOFU NGIN SAPIENS POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 70MG	CASPOFU NGIN SAPIENS POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION ZOMG	9029/22T 9030/22T	SAPIENS PHARMACEU	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 ASME
70MG	70MG	9029/22T, 9030/22T	TICALS LTD	ASMF
CASPOFU NGIN SAPIENS POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 50MG NOPRILAM	CASPOFU NGIN SAPIENS POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION 50MG NOPRILAM	9031/22T, 9032/22T	SAPIENS PHARMACEU TICALS 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
125	125			
POWDER	POWDER			
FOR ORAL	FOR ORAL			C.I.z C.I.z - SAFETY, EFFICACY,
SUSPENSI ON	SUSPENSI ON		BIAL-	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
(125MG/31.	(125MG/31.		PORTELA &	MEDICINAL PRODUCTS - Other
25MG)5ML	25MG)5ML	602/23T, 603/23T	CA, SA	variation
NOPRILAM	NOPRILAM			
250 POWDER	250 POWDER			
FOR ORAL	FOR ORAL			C.I.z C.I.z - SAFETY, EFFICACY,
SUSPENSI	SUSPENSI			PHARMACOVIGILANCE CHANGES -
ON (250MG/62.	ON (250MG/62.		BIAL- PORTELA &	HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other
(25010G/62. 5MG)/5ML	(250101G/62. 5MG)/5ML	600/23T, 601/23T	CA, SA	variation
NOPRILAM 500 TABLET,	NOPRILAM 500 TABLET,		BIAL-	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
FILM	FILM		PORTELA &	MEDICINAL PRODUCTS - Other
COATED	COATED	606/23T, 607/23T	CA, SA	variation

(500MG/12	(500MG/12 5MG)			
5MG) NOPRILAM DT TABLET, FILM COATED 1000MG	NOPRILAM DT 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
NOPRILAM DT POWDER FOR ORAL SUSPENSI ON (400MG/57 MG)/5ML	NOPRILAM DT POWDER FOR ORAL SUSPENSI ON (400MG/57 MG)/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
GLYFORMI N TABLET, FILM COATED 850MG	GLYFORMI N 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
GLYFORMI N TABLET, FILM COATED 500MG	GLYFORMI N 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
REPRAT GAST TABLET, GASTRO- RESISTAN T 20MG	REPRAT GAST TABLET, GASTRO- RESISTAN T 20MG	6171/23T, 6172/23T	DELORBIS PHARMACEU TICALS 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 BREEZHAL ER INHALATIO N POWDER IN CAPSULES 200MCG	MIFLONIDE BREEZHAL ER INHALATIO N 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 BREEZHAL ER INHALATIO N POWDER IN CAPSULES 400MCG	MIFLONIDE BREEZHAL ER INHALATIO N 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

r					B.II.b.2.a B.II.b.2.a - QUALITY
	LIPOPEN TABLET, FILM COATED 40MG/10M G	LIPOPEN TABLET, FILM COATED 40MG/10M G	4479/23T, 4480/23T, 4481/23T, 4482/23T	ELPEN PHARMACEU TICAL CO INC	CHANGES - FINISHED PRODUCT - Manufacture - Change to 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/10M G	LIPOPEN TABLET, FILM COATED 10MG/10M G	4487/23T, 4488/23T, 4489/23T, 4490/23T	ELPEN PHARMACEU TICAL 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 site for part or all of the manufacture - Replacement or addition of a manufacturing site for part or all of the 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 site for part or all of the manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing site for part or all of the 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 PHARMACEU TICAL 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 B.II.b.2.a B.II.b.2.a - QUALITY
				CHANGES - FINISHED PRODUCT -
				Manufacture - Change to 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
TABLET, FILM	TABLET, FILM			of a manufacturing site for part or all of the manufacturing process of the
COATED	COATED		ELPEN	finished product - Site where any
20MG/10M	20MG/10M	4483/23T, 4484/23T,	PHARMACEU TICAL CO INC	manufacturing operation(s) take place,
G	G	4485/23T, 4486/23T	TICAL CO INC	ex A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product, packaging site, manufacturer
				responsible for batch release, site
				where batch control takes place, or
				supplier of a starting material, reagent or excipient (when mentioned in the
				dossier)*
TEKOIS	TEKOIO			B.I.a.2.e B.I.a.2.e - QUALITY
TEKCIS RADIONUC	TEKCIS RADIONUC			CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the
LIDE	LIDE			manufacturing process of the active
GENERAT	GENERAT		CIS BIO	substance - Minor change to the
OR 2-50 GBq	OR 2-50 GBq	638/23T, 639/23T	INTERNATION AL	restricted part of an Active Substance Master File
BEROZOL	BEROZOL			B.III.1.a.2 B.III.1.a.2 - QUALITY
POWDER	POWDER			CHANGES - CEP/TSE/MONOGRAPHS
FOR SOLUTION	FOR SOLUTION			- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
FOR	FOR		SAPIENS	of Ph. Eur. certificate of suitability: For
INJECTION	INJECTION	FOFT/DOT	PHARMACEU	an active substance For a starting
40MG/VIAL	40MG/VIAL	5657/23T	TICALS LTD	material/reagent/intermediate used in

	-			
				the manufacturing process of 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.4.a B.II.b.4.a - QUALITY
UNIXAM SOLUTION FOR INJECTION 100MG/ML	UNIXAM SOLUTION FOR INJECTION 100MG/ML	5632/23T	CODAL- SYNTO LIMITED	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 A.5.b A.5.b - ADMINISTRATIVE
MYOVIEW KIT FOR RADIOPHA RMACEUTI CAL PREPARAT ION 0.23MG	MYOVIEW KIT FOR RADIOPHA RMACEUTI CAL PREPARAT ION 0.23MG	5677/23T	GE HEALTHCARE AS (NYDALEN)	CHANGES - Change in the name and/or address of a manufacturer/importer of the 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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	ADVECIT CAPSULE, HARD 140MG ADVECIT	5607/23T	DELORBIS PHARMACEU TICALS LTD	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
CAPSULE, HARD 100MG	CAPSULE, HARD 100MG	5608/23T	DELORBIS PHARMACEU TICALS LTD	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
ADVECIT CAPSULE, HARD 250MG ADVECIT	ADVECIT CAPSULE, HARD 250MG ADVECIT	5605/23T	DELORBIS PHARMACEU TICALS LTD	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation
CAPSULE, HARD 180MG	CAPSULE, HARD 180MG	5606/23T	DELORBIS PHARMACEU TICALS 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 PHARMACEU TICALS LTD DELORBIS	B.II.e.z B.II.e.z - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Other variation B.II.e.z B.II.e.z - QUALITY CHANGES -
ADVECIT CAPSULE,	ADVECIT CAPSULE,	5609/23T	PHARMACEU TICALS LTD	FINISHED PRODUCT - Container closure system - Other variation

HARD	HARD			
20MG	20MG			
ATARAX TABLET,	ATARAX TABLET,			
FILM	FILM			
COATED	COATED		UCB PHARMA	C.I.6 z) Change(s) to therapeutic
25MG	25MG	6255/20T	SA	indication(s) Other variation
ATARAX SYRUP	ATARAX SYRUP		UCB PHARMA	C.I.6 z) Change(s) to therapeutic
2MG/ML	2MG/ML	6254/20T	SA	indication(s) Other variation
ISOTROIN CAPSULE, SOFT 30MG	ISOTROIN CAPSULE, SOFT 30MG	3127/23T	IASIS PHARMACEU TICALS 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	HAVRIX			
ADULTS SUSPENSI ON FOR INJECTION 1440 ELISA UNIT/ML	ADULTS SUSPENSI ON FOR INJECTION 1440 ELISA UNIT/ML	5230/23T	GLAXOSMITH KLINE 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	HAVRIX			
JUNIOR SUSPENSI ON FOR INJECTION 720 ELISA UNIT/0.5ML	JUNIOR SUSPENSI ON FOR INJECTION 720 ELISA UNIT/0.5ML	5229/23T	GLAXOSMITH KLINE 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
PACLITAXE L ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 6MG/ML	PACLITAXE L ACCORD CONCENT RATE 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	FLUNOL CAPSULE, HARD	6539/23T, 6540/23T,	PHARMA Q	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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: 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: 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
100MG	100MG	6541/23T, 6542/23T	AE	material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - Eur
SELEMYCI N SOLUTION FOR INJECTION OR INFUSION 250MG/2ML	SELEMYCI N 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 C.I.2.a C.I.2.a - SAFETY, EFFICACY,
SELEMYCI N SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	SELEMYCI N SOLUTION FOR INJECTION OR INFUSION 100MG/2ML	510/23T	MEDOCHEMIE LTD	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
SELEMYCI N SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	SELEMYCI N SOLUTION FOR INJECTION OR INFUSION 500MG/2ML	511/23T	MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 SUSPENSI ON FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSI ON FOR INJECTION 1440 ELISA UNIT/ML	2508/22T	GLAXOSMITH KLINE 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 SUSPENSI ON FOR INJECTION 720 ELISA UNIT/0.5ML	HAVRIX JUNIOR SUSPENSI ON FOR INJECTION 720 ELISA UNIT/0.5ML	2507/22T	GLAXOSMITH KLINE 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.
PEMETREX ED SANDOZ CONCENT RATE FOR SOLUTION FOR INFUSION 25MG/ML	PEMETREX ED SANDOZ CONCENT RATE FOR SOLUTION FOR INFUSION 25MG/ML	808/23T	SANDOZ PHARMACEU TICALS 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	GLAXOSMITH KLINE (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 PHARMACEU TICALS 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

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

	I			T
				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
				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
ADVECIT	ADVECIT	5405/22T 5400/22T		an active substance For a starting
CAPSULE, HARD	CAPSULE, HARD	5485/23T, 5486/23T,	DELORBIS PHARMACEU	material/reagent/intermediate used in
20MG	20MG	5487/23T, 5488/23T, 5489/23T, 5490/23T	TICALS LTD	the manufacturing process of the active substance For an excipient - Eur
201010	201010	3489/231, 3490/231	TICALS 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.
	ADVECIT	5491/23T, 5492/23T,	DELORBIS	Eur. Certificate of suitability or deletion
ADVECIT				
ADVECIT CAPSULE, HARD 5MG	CAPSULE, HARD 5MG	5493/23T, 5494/23T, 5495/23T, 5496/23T	PHARMACEU TICALS LTD	of Ph. Eur. certificate 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
OPTODRO P EYE DROPS, SOLUTION	OPTODRO P EYE DROPS, SOLUTION	0575/007		C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other
2% W/V	2% W/V	3575/23T	RAFARM S.A.	
SUGAMMA DEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	SUGAMMA DEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	6843/23T	SAPIENS PHARMACEU TICALS 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)
PACLITAXE L HOSPIRA CONCENT RATE FOR SOLUTION FOR INFUSION 6MC/MI	PACLITAXE L HOSPIRA CONCENT RATE FOR SOLUTION FOR INFUSION 6MG(MI	3442/23T, 3443/23T, 3444/23T, 3445/23T	PFIZER	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 and
6MG/ML	6MG/ML	3444/23T, 3445/23T	HELLAS AE	internal test method and test method n B.I.a.3.a B.I.a.3.a - QUALITY
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	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 C.I.z C.I.z - SAFETY, EFFICACY,
SUTIREM CAPSULE, HARD 12.5MG	SUTIREM CAPSULE, HARD 12.5MG	5596/23T	REMEDICA LTD	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

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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
LOSATHIN A KOR TABLET, FILM COATED 100/25MG	LOSATHIN A KOR TABLET, FILM COATED 100/25MG	9300/22T	PHARMATHE N 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)
LOSATHIN A KOR TABLET, FILM COATED 50/12.5MG	LOSATHIN A KOR TABLET, FILM COATED 50/12.5MG	9301/22T	PHARMATHE N 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 PHARMACEU TICAL 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 PHARMACEU TICAL 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/10M G	AMODUO TABLET 10MG/10M G	5616/23T	WIN MEDICA PHARMACEU TICAL 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 SEVOFLUR	AMODUO TABLET 10MG/5MG	5617/23T	WIN MEDICA PHARMACEU TICAL S.A. (TRADING AS WIN MEDICA S.A.)	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.a.2.a B.I.a.2.a - QUALITY
ANE- PIRAMAL INHALATIO N VAPOUR, LIQUID 100% V/V	SEVOFLUR ANE- PIRAMAL INHALATIO N VAPOUR, LIQUID 100% V/V	5676/23T	PIRAMAL CRITICAL CARE B.V.	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 INTERNATION AL OPERATIONS LUXEMBOUR G 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 INTERNATION AL OPERATIONS LUXEMBOUR G 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/25M G	OLARTAN- PLUS TABLET, FILM COATED 20MG/25M G	5163/23T, 5164/23T	MENARINI INTERNATION AL OPERATIONS LUXEMBOUR G 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/25M G	OLARTAN- PLUS TABLET, FILM COATED 40MG/25M G	5159/23T, 5160/23T	MENARINI INTERNATION AL OPERATIONS LUXEMBOUR G 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 INTERNATION AL OPERATIONS LUXEMBOUR G 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 INTERNATION AL OPERATIONS LUXEMBOUR G 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 INTERNATION AL OPERATIONS LUXEMBOUR G 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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
BENZHEXO L TABLET 5MG	BENZHEXO L 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
NOPRILAM DT TABLET, FILM COATED 1000MG	NOPRILAM DT 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	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 20 MUTER	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, CHEWABL E 500MG/250 MG	ALUTRIL FORTE TABLET, CHEWABL E 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- RESISTAN T 5MG	LAX-TAB TABLET, GASTRO- RESISTAN T 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 ARZNEIMITTE L 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
				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
TRAVOCO	TRAVOCO	6462/22T, 6463/22T,	LEO PHARMA	manufacturer (including where relevant quality control testing sites) of the active
RT CREAM	RT CREAM	6464/22T, 6465/22T	A/S	substance, where no Ph. Eur. C
				A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing sites for an active substance.
				intermediate or finished product,
				packaging site, manufacturer
			GLAXOSMITH	responsible for batch release, site where batch control takes place, or
ZOVIRAX	ZOVIRAX		KLINE	supplier of a starting material, reagent
CREAM 5%	CREAM 5%		(IRELAND)	or excipient (when mentioned in the
W/W	W/W	5436/23T	LIMITED	dossier)* A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer responsible for batch release, site
DERMOVA	DERMOVA		GLAXOSMITH	where batch control takes place, or
TE	TE		KLINE	supplier of a starting material, reagent
OINTMENT 0.05% W/W	OINTMENT 0.05% W/W	5433/23T	(IRELAND) LIMITED	or excipient (when mentioned in the dossier)*
	0.0070 11/14			A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance, intermediate or finished product,
				packaging site, manufacturer
				responsible for batch release, site
BETNOVAT	BETNOVAT		GLAXOSMITH KLINE	where batch control takes place, or supplier of a starting material, reagent
E CREAM	E CREAM		(IRELAND)	or excipient (when mentioned in the
0.1% W/W	0.1% W/W	5435/23T	LIMITED	dossier)*
				A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer
			GLAXOSMITH	responsible for batch release, site where batch control takes place, or
DERMOVA	DERMOVA		KLINE	supplier of a starting material, reagent
TE CREAM	TE CREAM	5 40 4/00T	(IRELAND)	or excipient (when mentioned in the
0.05% W/W	0.05% W/W	5434/23T	LIMITED	dossier)*

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LORYTEC TABLET 10MG	LORYTEC TABLET 10MG	4774/23T	DELORBIS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
METRONID	METRONID			 B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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
AZOLE TABLET 200MG	AZOLE TABLET 200MG	6151/23T, 6152/23T, 6153/23T	REMEDICA LTD	substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Active substance
METRONID AZOLE TABLET	METRONID AZOLE TABLET	6154/23T, 6155/23T,	REMEDICA	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate 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
250MG NICORETT E CLEAR	250MG NICORETT E CLEAR	6156/23T	JOHNSON & JOHNSON	of a Member State - Active substance B.II.d.z B.II.d.z - QUALITY CHANGES - FINISHED PRODUCT - Control of
PATCH	PATCH	5034/21T	HELLAS	finished product - Other variation

PATCH,	PATCH,		CONSUMER	
TRANSDER	TRANSDER		AE	
MAL 25MG/16h	MAL 25MG/16h			
NICORETT E CLEAR	NICORETT E CLEAR			
PATCH	PATCH		JOHNSON &	
PATCH,	PATCH,		JOHNSON	
TRANSDER	TRANSDER		HELLAS	B.II.d.z B.II.d.z - QUALITY CHANGES -
MAL	MAL		CONSUMER	FINISHED PRODUCT - Control of
15MG/16h	15MG/16h	5035/21T	AE	finished product - Other variation
NICORETT	NICORETT			
E CLEAR	E CLEAR			
PATCH			JOHNSON &	
PATCH, TRANSDER	PATCH, TRANSDER		JOHNSON HELLAS	B.II.d.z B.II.d.z - QUALITY CHANGES -
MAL	MAL		CONSUMER	FINISHED PRODUCT - Control of
10MG/16h	10MG/16h	5033/21T	AE	finished product - Other variation
				C.I.z C.I.z - SAFETY, EFFICACY,
VORICONA	VORICONA			PHARMACOVIGILANCE CHANGES -
ZOLE	ZOLE			HUMAN AND VETERINARY
FRESENIU	FRESENIU			MEDICINAL PRODUCTS - Change(s)
S KABI	S KABI			in the Summary of product
POWDER FOR	POWDER FOR			Characteristics, Labelling or Package Leaflet intended to implement the
SOLUTION	SOLUTION			outcome of a PRAC signal
FOR	FOR		FRESENIUS	recommendation: implementation of
INFUSION	INFUSION		KABI HELLAS	wording agreed by the competent
200MG/VIA	200MG/VIA		SINGLE	authority that do not require any further
L	L	4946/23T	MEMBER S.A.	assessment
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of 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
XYLOCREA	XYLOCREA			Pharmacopoeial Certificate of Suitability
M CREAM	M CREAM		VERISFIELD	to the relevant Ph. Eur. Monograph -
(2.5+2.5)%	(2.5+2.5)%	5823/23T, 5824/23T,	SINGLE	New certificate from an already
Ŵ/W	W/W	5825/23T	MEMBER S.A.	approved manufacturer
REMABIRA	REMABIRA			B.II.e.5.b B.II.e.5.b - QUALITY
T TABLET,	T TABLET,			CHANGES - FINISHED PRODUCT -
FILM COATED	FILM COATED		REMEDICA	Container closure system - Change in pack size of the finished product -
1000MG	1000MG	4783/23T	LTD	Deletion of pack size(s)
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
			DOFUENCES	in the Summary of Product
			BOEHRINGER	Characteristics, Labelling or Package
MOVATEC TABLET	MOVATEC TABLET		INGELHEIM INTERNATION	Leaflet of human medicinal products intended to implement the outcome of a
15MG	15MG	5822/23T	AL GMBH	procedure concerning PSUR or PASS,
10110	10110			

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				or the outcome of 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 INTERNATION AL 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
VAXIGRIPT ETRA SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 15MCG/DO SE	VAXIGRIPT ETRA SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 15MCG/DO SE	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
REMABIRA T TABLET, FILM COATED 250MG	REMABIRA T TABLET, FILM COATED 250MG	4781/23T, 4782/23T	REMEDICA	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
REMABIRA T TABLET, FILM COATED 500MG	REMABIRA T 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/25M G	LEVOMED TABLET 100MG/25M G	4700/23T	MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH

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LEVOMED TABLET 250MG/25M G	LEVOMED TABLET 250MG/25M G	4699/23T	MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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/10M G	LEVOMED TABLET 100MG/10M G	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 BIOPRODUCT S 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 EFFERVES CENT TABLET 500MG	CALCIUM- SANDOZ FORTE EFFERVES CENT TABLET 500MG	5702/23T	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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	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, PROLONG ED- RELEASE 5MG/50MG	LOGIMAX TABLET, PROLONG ED- 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

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				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)
URICHOFE B TABLET, FILM COATED 80MG	URICHOFE B TABLET, FILM COATED 80MG	6535/22T	WIN MEDICA PHARMACEU TICAL 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
URICHOFE B TABLET, FILM COATED 120MG	URICHOFE B TABLET, FILM COATED 120MG	6536/22T	WIN MEDICA PHARMACEU TICAL 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
LATANOPR OST DEMO EYE DROPS, SOLUTION 50MCG/ML	LATANOPR OST 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
CARBOPLA TIN/HOSPI RA SOLUTION FOR INFUSION 10MG/ML	CARBOPLA TIN/HOSPI RA 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	GLAXOSMITH KLINE 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 SUSPENSI ON 250MG/5ML	ZINNAT GRANULES FOR ORAL SUSPENSI ON 250MG/5ML	4340/23T	SANDOZ PHARMACEU TICALS 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	HUMAN ALBUMIN BAXALTA SOLUTION FOR INFUSION 250G/L HUMAN ALBUMIN BAXALTA SOLUTION	5665/23T 5666/23T	BAXALTA INNOVATIONS GMBH 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 B.V.a.1.d B.V.a.1.d - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - PMF/VAMF -

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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
TRISEQUE NS 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 CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSION 5MG	5696/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSION 2MG	5697/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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 CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSION 1MG	5698/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
/HYDROCH LOROTHIA ZIDE KRKA TABLET, FILM COATED 100MG/25M G LOSARTAN /HYDROCH	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 B.II.b.3.a B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the
	200G/L TRISEQUE NS TABLET, FILM COATED REFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSION 5MG REFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSION 2MG REFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSION 2MG REFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSION 2MG REFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSION 1MG LOSARTAN /HYDROCH LOSARTAN	200G/LTRISEQUE NS TABLET, FILM COATEDABLET, FILM COATEDREFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSION SMGREFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INJECTION OR INJECTION OR SOLUTION FOR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INFUSION ZMGREFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSION ZMGREFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INJECTION OR S698/23TCOACENT RATE FOR SOLUTION FOR INJECTION OR INJECTION OR INJECTION OR INJECTION OR INFUSION 1MG2005ARTAN /HYDROCH LOSARTAN IOGMC/25M G5437/23T, 5438/23T	200G/LNOVOTRISEQUE NS TABLET, FILM COATEDNOVOREFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INJECTION OR INFUSIONNOVO HELLAS LTDREFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSIONSAPIENS PHARMACEU TICALS LTDREFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSIONSAPIENS PHARMACEU TICALS LTDREFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSIONSAPIENS PHARMACEU TICALS LTDREFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION ZMGSAPIENS PHARMACEU TICALS LTDREFENTA POWDER FOR NGUTION FOR INFUSION ZMGSAPIENS PHARMACEU TICALS LTDREFENTA POWDER FOR CONCENT RATE FOR SOLUTION FOR INFUSION ZMGSAPIENS PHARMACEU TICALS LTDREFENTA POR CONCENT RATE FOR SOLUTION FOR INFUSION CONCENT RATE FOR SOLUTION FOR CONCENT RATE FOR SOLUTION FOR INFUSION CONCENT RATE FOR SAPIENS PHARMACEU TICALS LTDREFENTA POR CONCENT RATE FOR SOLUTION FOR INFUSION CONCENT RATE FOR SAPIENS PHARMACEU TICALS LTDREFENTA POR CONCENT RATE FOR SOLUTION FOR INFUSION CONCENT RATE FOR SAPIENS PHARMACEU TICALS LTDREFENTA POR CONCENT RATE FOR SOLUTION FOR SAPIENS PHARMACEU TICALS LTDREFENTA POR CONCENT RATE FOR SAPIENS PHARMACEU TICALS LTDREFENTA POR CONCENT CONCENT RATE FOR SAPIENS PHARMACEU<

TABLET, FILM COATED	TABLET, FILM COATED			product, including an intermediate used in the manufacture of the finished product - Minor change in the
50MG/12.5 MG	50MG/12.5 MG			manufacturing process
NEURONTI N CAPSULE, HARD 300MG	NEURONTI N 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
NEURONTI N CAPSULE, HARD 400MG	NEURONTI N 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
NEURONTI N CAPSULE, HARD 300MG	NEURONTI N 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
NEURONTI N CAPSULE, HARD 400MG	NEURONTI N 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
ROSUVAST ATIN ACINO TABLET, FILM COATED 40MG ROSUVAST ATIN ACINO TABLET, FILM COATED 5MG	ROSUVAST ATIN ACINO TABLET, FILM COATED 40MG ROSUVAST ATIN ACINO TABLET, FILM COATED 5MG	2338/23T 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 C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the

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				outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
ROSUVAST ATIN ACINO TABLET, FILM COATED 10MG	ROSUVAST ATIN 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
ROSUVAST ATIN ACINO TABLET, FILM COATED 20MG	ROSUVAST ATIN 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	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 OPHTHAL MIC EYE DROPS, SOLUTION	COSOPT OPHTHAL MIC 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 PHARMACEU TICALS 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

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				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
				B.II.d.1.c B.II.d.1.c - QUALITY
				CHANGES - FINISHED PRODUCT -
IMODIUM	IMODIUM		JOHNSON &	Control of finished product - Change in the specification parameters and/or
PLUS	PLUS		JOHNSON	limits of the finished product - Addition
TABLET	TABLET		HELLAS	of a new specification parameter to the
2MG/125M	2MG/125M		CONSUMER	specification with its corresponding test
G	G	8187/22T	AE	method
LEDRAXEN	LEDRAXEN			B.I.b.1.z B.I.b.1.z - QUALITY
SOLUTION	SOLUTION			CHANGES - ACTIVE SUBSTANCE -
FOR	FOR			Control of active substance - Change in
INJECTION	INJECTION			the specification parameters and/or
IN	IN			limits of an active substance, starting
PREFILLED	PREFILLED			material / intermediate / reagent used in
SYRINGE	SYRINGE	4944/23T	VENIPHARM	the manufacturing process of the active
4000IU LEDRAXEN	4000IU LEDRAXEN	4944/231	VENIFIARIVI	substance - Other changes B.I.b.1.z B.I.b.1.z - QUALITY
SOLUTION	SOLUTION			CHANGES - ACTIVE SUBSTANCE -
FOR	FOR			Control of active substance - Change in
INJECTION	INJECTION			the specification parameters and/or
IN	IN			limits of an active substance, starting
PREFILLED	PREFILLED			material / intermediate / reagent used in
SYRINGE	SYRINGE			the manufacturing process of the active
2000IU	2000IU	4945/23T	VENIPHARM	substance - Other changes
LEDRAXEN	LEDRAXEN			B.I.b.1.z B.I.b.1.z - QUALITY
SOLUTION FOR	SOLUTION FOR			CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in
INJECTION	INJECTION			the specification parameters and/or
IN	IN			limits of an active substance, starting
PREFILLED	PREFILLED			material / intermediate / reagent used in
SYRINGE	SYRINGE			the manufacturing process of the active
6000IU	6000IU	4943/23T	VENIPHARM	substance - Other changes
LEDRAXEN	LEDRAXEN			B.I.b.1.z B.I.b.1.z - QUALITY
SOLUTION	SOLUTION			CHANGES - ACTIVE SUBSTANCE -
FOR	FOR			Control of active substance - Change in
INJECTION	INJECTION IN			the specification parameters and/or limits of an active substance, starting
PREFILLED	PREFILLED			material / intermediate / reagent used in
SYRINGE	SYRINGE			the manufacturing process of the active
10000IU	10000IU	4941/23T	VENIPHARM	substance - Other changes
LEDRAXEN	LEDRAXEN			B.I.b.1.z B.I.b.1.z - QUALITY
SOLUTION	SOLUTION			CHANGES - ACTIVE SUBSTANCE -
FOR	FOR			Control of active substance - Change in
INJECTION	INJECTION			the specification parameters and/or
IN	IN			limits of an active substance, starting
PREFILLED	PREFILLED			material / intermediate / reagent used in
SYRINGE 8000IU	SYRINGE 8000IU	4942/23T	VENIPHARM	the manufacturing process of the active substance - Other changes
RIASTAP	RIASTAP			Substance - Other Changes
POWDER	POWDER			
FOR	FOR			B.II.d.2.a B.II.d.2.a - QUALITY
SOLUTION	SOLUTION			CHANGES - FINISHED PRODUCT -
FOR	FOR			Control of finished product - Change in
INJECTION	INJECTION			test procedure for the finished product -
/INFUSION	/INFUSION		CSL BEHRING	Minor changes to an approved test
1G	1G	5386/23T, 5387/23T	GMBH	procedure

			FARCO-	- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
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 B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
MOXICLAV TABLET, FILM COATED 625MG	MOXICLAV TABLET, FILM COATED 625MG	5686/23T, 5687/23T	MEDOCHEMIE	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 1G	MOXICLAV TABLET, FILM COATED 1G	5690/23T, 5691/23T	MEDOCHEMIE	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
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

				the manufacturing process of 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/1.2 0MG	SORIL- MED HONEY & LEMON LOZENGE 0.60MG/1.2 0MG	6060/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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	ARCHIFAR POWDER FOR SOLUTION FOR INJECTION /INFUSION 500MG ARCHIFAR POWDER FOR SOLUTION FOR	5646/23T	MEDOCHEMIE LTD MEDOCHEMIE	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For

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/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
TARGINAC T TABLET, PROLONG ED- RELEASE 5/2.5MG	TARGINAC T TABLET, PROLONG ED- RELEASE 5/2.5MG	1290/23T	MUNDIPHARM A PHARMACEU TICALS 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
TARGINAC T TABLET, PROLONG ED- RELEASE 10/5MG	TARGINAC T TABLET, PROLONG ED- RELEASE 10/5MG	1293/23T	MUNDIPHARM A PHARMACEU TICALS 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
TARGINAC T TABLET, PROLONG ED- RELEASE 40/20MG	TARGINAC T TABLET, PROLONG ED- RELEASE 40/20MG	1291/23T	MUNDIPHARM A PHARMACEU TICALS 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
TARGINAC T TABLET, PROLONG ED- RELEASE 20/10MG	TARGINAC T TABLET, PROLONG ED- RELEASE 20/10MG	1292/23T	MUNDIPHARM A PHARMACEU TICALS 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 INJECTABL E POWDER FOR SOLUTION FOR INFUSION 500MG/VIA L	AZITHRAN INJECTABL E POWDER FOR SOLUTION FOR INFUSION 500MG/VIA L	968/23T	SAPIENS PHARMACEU TICALS 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
SYNTOQUI P TABLET, FILM COATED 1MG	SYNTOQUI P 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

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				1901/2006 - Implementation of wording agreed by the competent authority
SYNTOQUI P TABLET, FILM COATED 0.25MG	SYNTOQUI P 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
SYNTOQUI P TABLET, FILM COATED 2MG	SYNTOQUI P 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
SYNTOQUI P TABLET, FILM COATED 0.5MG	SYNTOQUI P 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
SYNTOQUI P TABLET, FILM COATED 5MG	SYNTOQUI P 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
PAZOCTA M POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/ VIAL GABAPENT	PAZOCTA M POWDER FOR SOLUTION FOR INFUSION (4G/0.5G)/ VIAL GABAPENT	6388/23T	SAPIENS PHARMACEU TICALS LTD ACCORD	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.2.c B.II.e.2.c - QUALITY
IN ACCORD	IN ACCORD	6207/23T, 6208/23T	HEALTHCARE S.L.U	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
GABAPENT IN ACCORD CAPSULE, HARD 400MG	GABAPENT IN 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
FINGOLIM OD PHARMAS CIENCE CAPSULE, HARD 0.5MG	FINGOLIM OD PHARMAS CIENCE CAPSULE, HARD 0.5MG	3320/23T	PHARMASCIE NCE INTERNATION AL 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)
VINORELBI NE ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 10MG/ML	VINORELBI NE ACCORD CONCENT RATE 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/VI AL	CEFURAX POWDER FOR SOLUTION FOR INJECTION /INFUSION 1500MG/VI AL	5700/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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/VIA L	CEFURAX POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG/VIA L	5701/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability

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				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 PHARMACEU TICALS 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 PHARMACEU TICALS 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,	ALZEDEM TABLET,			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, Manufacture - Change to importer,
FILM COATED 20MG	FILM COATED 20MG	5284/23T, 5285/23T, 5286/23T, 5287/23T	CODAL- SYNTO LIMITED	batch release arrangements and quality control testing of the finished product - Replacement or addition of a

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				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 manufacture 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,
ALZEDEM TABLET, FILM COATED 10MC	ALZEDEM TABLET, FILM COATED 10MG	5292/23T, 5293/23T, 5294/23T, 5293/23T,	CODAL- SYNTO	ex 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,
PLATOREL TABLET, FILM COATED	PLATOREL TABLET, FILM COATED	5294/23T, 5295/23T	ELPEN PHARMACEU	ex C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the
10MG PLATOREL TABLET, FILM COATED 40MG	10MG PLATOREL TABLET, FILM COATED 40MG	2475/23T 2473/23T	ELPEN PHARMACEU TICAL CO INC	MAH C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH
PLATOREL TABLET, FILM COATED 20MG	PLATOREL TABLET, FILM COATED 20MG	2474/23T	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
PLATOREL TABLET, FILM COATED 5MG	PLATOREL TABLET, FILM COATED 5MG	2476/23T	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
PLATOREL TABLET, FILM COATED 10MG	PLATOREL TABLET, FILM COATED 10MG	2372/23T	ELPEN PHARMACEU TICAL 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 PHARMACEU TICAL 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 PHARMACEU TICAL 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 PHARMACEU TICAL 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
PANTOPRA ZOLE DELORBIS TABLET, GASTRO- RESISTAN T 40MG	PANTOPRA ZOLE DELORBIS TABLET, GASTRO- RESISTAN T 40MG	6145/23T, 6146/23T	DELORBIS PHARMACEU TICALS 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

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				B.II.z B.II.z - QUALITY CHANGES - FINISHED PRODUCT - Other variation
VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIA L	VANCO SAPIENS POWDER FOR SOLUTION FOR INFUSION 500MG/VIA	4697/23T, 4698/23T	SAPIENS PHARMACEU TICALS 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 PHARMACEU TICALS 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
ACETAZOL AMIDE TABLET 250MG	ACETAZOL AMIDE 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 SUSPENSI ON (125MG/31. 25MG)5ML	NOPRILAM 125 POWDER FOR ORAL SUSPENSI ON (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 SUSPENSI ON (250MG/62. 5MG)/5ML	NOPRILAM 250 POWDER FOR ORAL SUSPENSI ON (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 POWDER	NOPRILAM DT TABLET, FILM COATED 1000MG NOPRILAM DT POWDER	1582/23T	BIAL- PORTELA & CA, SA 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 C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY

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FOR ORAL	FOR ORAL			MEDICINAL PRODUCTS - Change(s)
SUSPENSI ON	SUSPENSI ON			in the Summary of Product Characteristics, Labelling or Package
(400MG/57	(400MG/57			Leaflet of human medicinal products
MG)/5ML	MG)/5ML			intended to implement the outcome of a
INIC//ONIE	WO//ONE			procedure concerning PSUR or PASS,
				or the outcome of 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.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
NOPRILAM	NOPRILAM			intended to implement the outcome of a procedure concerning PSUR or PASS,
500 TABLET,	500 TABLET,			or the outcome of the assessment done
FILM	FILM			by the competent authority under
COATED	COATED		BIAL-	Articles 45 or 46 of Regulation
(500MG/12	(500MG/12		PORTELA &	1901/2006 - Implementation of wording
5MG)	5MG)	1583/23T	CA, SA	agreed by the competent authority
			,	B.II.f.1.d B.II.f.1.d - QUALITY
				CHANGES - FINISHED PRODUCT -
SOLIAN	SOLIAN			Stability - Change in the shelf-life or
TABLET,	TABLET,			storage conditions of the finished
FILM	FILM		SANOFI	product - Change in storage conditions
COATED	COATED		WINTHROP	of the finished product or the
400MG	400MG	4430/23T	INDUSTRIE.	diluted/reconstituted product
				A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing
				sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer
				responsible for batch release, site
				where batch control takes place, or
SOLIAN	SOLIAN			supplier of a starting material, reagent
TABLET,	TABLET,		SANOFI	or excipient (when mentioned in the
FILM COATED	FILM COATED		WINTHROP	dossier)* A.z A.z - ADMINISTRATIVE CHANGES
400MG	400MG	3181/23T, 3182/23T	INDUSTRIE.	- Other variation
400000	400000	0101/201, 0102/201	INDOOTHIE.	B.II.d.2.e B.II.d.2.e - QUALITY
			MENARINI	CHANGES - FINISHED PRODUCT -
			INTERNATION	Control of finished product - Change in
BILAZ	BILAZ		AL	test procedure for the finished product -
ORAL	ORAL		OPERATIONS	Update of the test procedure to comply
SOLUTION	SOLUTION		LUXEMBOUR	with the updated general monograph in
2.5MG/ML	2.5MG/ML	5501/23T	G SA	the Ph. Eur.
				C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of product
				Characteristics, Labelling or Package
TRIVERAM	TRIVERAM			Leaflet intended to implement the
TABLET,	TABLET,			outcome of a PRAC signal
FILM	FILM			recommendation: implementation of
COATED	COATED		LES	wording agreed by the competent
20MG/5MG/	20MG/5MG/	2024/227		authority that do not require any further
5MG	5MG	3231/23T	ES SERVIER	
				C.I.Z C.I.Z - SAFETY, EFFICACY,
TRIVERAM TABLET,	TRIVERAM TABLET,			PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
FILM	FILM			MEDICINAL PRODUCTS - Change(s)
	COATED		LES	in the Summary of product
40MG/10M	40MG/10M		LABORATOIR	Characteristics, Labelling or Package
G/10MG	G/10MG	3234/23T	ES SERVIER	Leaflet intended to implement the
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				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/10M G/10MG	TRIVERAM TABLET, FILM COATED 20MG/10M G/10MG	3233/23T	LES LABORATOIR ES 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 LABORATOIR ES 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/10M G/5MG	TRIVERAM TABLET, FILM COATED 20MG/10M G/5MG	3232/23T	LES LABORATOIR ES 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
CHORIOM ON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	CHORIOM ON POWDER AND SOLVENT FOR SOLUTION FOR INJECTION 5000IU	6405/23T, 6406/23T, 6407/23T, 6408/23T, 6409/23T, 6410/23T	IBSA FARMACEUTI CI 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) B.III.1.a.2 B.III.1.a.2 - QUALITY
AZITHRAN TABLET, FILM COATED 500MG	AZITHRAN TABLET, FILM COATED 500MG	912/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting

material/reagent/intermediate used in material/reagent/intermediate used in the manufacturing process of the act substance For an excipient - Europe Pharmacopoeial Certificate of Suitab to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or additi of a manufacturing site for part or all the manufacturing process of the	ve an
Pharmacopoeial Certificate of Suitab to the relevant Ph. Eur. Monograph Updated certificate from an already approved manufacturer B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT Manufacture - Replacement or additi of a manufacturing site for part or all	
to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 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	inty
Updated certificate from an already approved manufacturer B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT Manufacture - Replacement or additi of a manufacturing site for part or all	
B.II.b.1.e B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT Manufacture - Replacement or additi of a manufacturing site for part or all	
CHANGES - FINISHED PRODUCT Manufacture - Replacement or additi of a manufacturing site for part or all	
Manufacture - Replacement or additi of a manufacturing site for part or all	
of a manufacturing site for part or all	
the manufacturing process of the	
finished product - Site where any	
manufacturing operation(s) take place	ə,
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 qua	lity
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 finishe	ł
product, including an intermediate us	
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	
MANTOME MANTOME Manufacture - Change to in-process D TABLET, D TABLET, tests or limits applied during the	
FILM FILM manufacture of the finished product	
COATED COATED 4444/23T, 4445/23T, MEDOCHEMIE Deletion of a non-significant in-proce	SS
20MG 20MG 4446/23T, 4447/23T LTD test B.II.b.1.e B.II.b.1.e - QUALITY B.II.b.1.e B.II.b.1.e - QUALITY B.II.b.1.e B.II.b.1.e - QUALITY	
CHANGES - FINISHED PRODUCT	
Manufacture - Replacement or additi of a manufacturing site for part or all	
the manufacturing process of the	J
finished product - Site where any	
manufacturing operation(s) take place	э,
ex B.II.b.2.c.2 B.II.b.2.c.2 - QUALITY	
CHANGES - FINISHED PRODUCT	
Manufacture - Change to importer,	124
batch release arrangements and qua 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 finisher product, including an intermediate us	
in the manufacture of the finished	eu
product - Minor change in the	
manufacturing proc B.II.b.5.c B.II.b.5.c - QUALITY	
B.II.D.S.C B.II.D.S.C - QUALITY CHANGES - FINISHED PRODUCT	
MANTOME MANTOME Manufacture - Change to in-process	
D TABLET, D TABLET, tests or limits applied during the	
D TABLET, D TABLET, tests or limits applied during the FILM FILM manufacture of the finished product - COATED COATED 4448/23T, 4449/23T,	

MANTOME D TABLET, FILM COATED 15MG	MANTOME D TABLET, FILM COATED 15MG	4436/23T, 4437/23T, 4438/23T, 4439/23T	MEDOCHEMIE	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
MANTOME D TABLET, FILM COATED 5MQ	MANTOME D TABLET, FILM COATED 5MG	4440/23T, 4441/23T, 4442/23T, 4443/23T	MEDOCHEMIE	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 PHARMACEU TICALS 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 DERMOVA	BETACORT CREAM DERMOVA	4758/23T	MEDICAIR BIOSCIENCE LABORATORI ES CY LTD GLAXOSMITH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
TE OINTMENT 0.05% W/W	TE OINTMENT 0.05% W/W	5507/23T	KLINE (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
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	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
BENDAMU STINE ACCORD CONCENT RATE FOR SOLUTION FOR INFUSION 25MG/ML	BENDAMU STINE ACCORD CONCENT RATE 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
DULOXETI NE ACCORD GASTRO- RESISTAN T CAPSULE, HARD 60MG	DULOXETI NE ACCORD GASTRO- RESISTAN T CAPSULE, HARD 60MG	4244/20T, 4245/20T	ACCORD HEALTHCARE S.L.U	B.III.1 a) 2. Updated certificate from an already approved manufacturer
DULOXETI NE ACCORD GASTRO-	DULOXETI NE ACCORD GASTRO-	4242/20T, 4243/20T	ACCORD HEALTHCARE S.L.U	B.III.1 a) 2. Updated certificate from an already approved manufacturer

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RESISTAN T	RESISTAN T			
CAPSULE, HARD 30MG	CAPSULE, HARD 30MG			
DULOXETI	DULOXETI			
NE ACCORD	NE ACCORD			
GASTRO-	GASTRO-			
RESISTAN	RESISTAN			D III 1 h) 2 Now cortificate for a starting
T CAPSULE,	T CAPSULE,		ACCORD	B.III.1 b) 2. New certificate for a starting material/reagent/intermediate/or
HARD	HARD	729 <i>4/</i> 20T	HEALTHCARE	excipient from a new or an already
60MG DULOXETI	60MG DULOXETI	7384/20T	S.L.U	approved manufacturer
NE	NE			
ACCORD GASTRO-	ACCORD GASTRO-			
RESISTAN	RESISTAN			
T CAPSULE,	T CAPSULE,		ACCORD	B.III.1 b) 2. New certificate for a starting material/reagent/intermediate/or
HARD	HARD	7005/007	HEALTHCARE	excipient from a new or an already
30MG	30MG	7385/20T	S.L.U	approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
				the manufacturing process of the active
EMFORAL	EMFORAL			substance For an excipient - European
TABLET, FILM	TABLET, FILM			Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
COATED	COATED	5500/00T	REMEDICA	Updated certificate from an already
40MG	40MG	5502/23T	LTD	approved manufacturer B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
				the manufacturing process of the active
EMFORAL TABLET,	EMFORAL TABLET,			substance For an excipient - European Pharmacopoeial Certificate of Suitability
FILM	FILM			to the relevant Ph. Eur. Monograph -
COATED 10MG	COATED 10MG	5503/23T	REMEDICA LTD	Updated certificate from an already approved manufacturer
				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
		6940/22T, 6941/22T,		identification test for a colouring or
		6942/22T, 6943/22T, 8820/22T, 8821/22T,		flavouring material) B.II.d.1.a B.II.d.1.a - QUALITY
		1 0020/221,0021/221,	1	
TRAVOCO RT CREAM	TRAVOCO	8822/22T, 8823/22T,	LEO PHARMA	CHANGES - FINISHED PRODUCT - Control of finished product - Change in

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				the specification parameters and/or limits of the finished product -
				Tightening of specification limits
EVECET TABLET, PROLONG ED- RELEASE 3MG	EVECET TABLET, PROLONG ED- RELEASE 3MG	7715/22T	P T HADJIGEORGI OU 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
				C.I.2.a C.I.2.a - SAFETY, EFFICACY,
EVECET TABLET, PROLONG ED- RELEASE 8MG	EVECET TABLET, PROLONG ED- RELEASE 8MG	7713/22T	P T HADJIGEORGI OU CO LTD	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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, PROLONG ED- RELEASE 4MG	EVECET TABLET, PROLONG ED- RELEASE 4MG	7714/22T	P T HADJIGEORGI OU 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, PROLONG ED- RELEASE 2MG	EVECET TABLET, PROLONG ED- RELEASE 2MG	7716/22T	P T HADJIGEORGI OU 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 CONCENT RATE FOR SOLUTION FOR INFUSION 1MG/ML	CISPLATIN CONCENT RATE 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, PROLONG ED- RELEASE 8MG	EVECET TABLET, PROLONG ED- RELEASE 8MG	5414/20T	P T HADJIGEORGI OU CO LTD	C.I.3 a) Implementation of wording agreed by the competent authority

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EVECET	EVECET			
TABLET, PROLONG	TABLET, PROLONG			
ED-	ED-		РТ	
RELEASE	RELEASE		HADJIGEORGI	C.I.3 a) Implementation of wording
3MG	3MG	5416/20T	OU CO LTD	agreed by the competent authority
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG ED-	PROLONG ED-		РТ	
RELEASE	RELEASE		HADJIGEORGI	C.I.3 a) Implementation of wording
4MG	4MG	5415/20T	OU CO LTD	agreed by the competent authority
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG	PROLONG		DT	
ED- RELEASE	ED- RELEASE		P T HADJIGEORGI	C.I.3 a) Implementation of wording
2MG	2MG	5417/20T	OU CO LTD	agreed by the competent authority
21010	21010	3417/201		C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
AMBRISEN	AMBRISEN			Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
TAN	TAN			medicinal products following
ACCORD	ACCORD			assessment of the same change for the
TABLET,	TABLET,			reference product - Implementation of
FILM	FILM		ACCORD	change(s) for which no new additional
COATED 10MG	COATED 10MG	1501/23T	HEALTHCARE S.L.U	data is required to be submitted by the MAH
TONIG	TOIMG	1501/251	3.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
AMBRISEN	AMBRISEN			Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
TAN	TAN			medicinal products following
ACCORD	ACCORD			assessment of the same change for the
TABLET,	TABLET,			reference product - Implementation of
FILM	FILM		ACCORD	change(s) for which no new additional
COATED 5MG	COATED 5MG	1502/23T	HEALTHCARE S.L.U	data is required to be submitted by the MAH
LIDOCAINE	LIDOCAINE	1302/231	3.L.U	
HYDROCH	HYDROCH			B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
LORIDE	LORIDE			CHANGES - FINISHED PRODUCT -
NORIDEM	NORIDEM			Stability - Change in the shelf-life or
SOLUTION FOR	SOLUTION FOR		NORIDEM	storage conditions of the finished
INJECTION	INJECTION		ENTERPRISE	product - Extension of the shelf life of the finished product - As packaged for
20 MG/ML	20 MG/ML	1703/23T	SLTD	sale (supported by real time data)
LIDOCAINE	LIDOCAINE			
HYDROCH	HYDROCH			B.II.f.1.b.1 B.II.f.1.b.1 - QUALITY
				CHANGES - FINISHED PRODUCT -
NORIDEM SOLUTION	NORIDEM SOLUTION			Stability - Change in the shelf-life or storage conditions of the finished
FOR	FOR		NORIDEM	product - Extension of the shelf life of
INJECTION	INJECTION		ENTERPRISE	the finished product - As packaged for
10 MG/ML	10 MG/ML	1704/23T	SLTD	sale (supported by real time data)
				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 of deletion
ADAGREL	ADAGREL			an active substance For a starting
TABLET,	TABLET,			material/reagent/intermediate used in
FILM	FILM		SAPIENS	the manufacturing process of the active
COATED	COATED	5521/22T	PHARMACEU	substance For an excipient - European
75MG	75MG	5531/23T	TICALS LTD	Pharmacopoeial Certificate of Suitability

				to the velociest Dh. Even Management
				to the relevant Ph. Eur. Monograph - New certificate from an already
				approved manufacturer
EZETIMIBE	EZETIMIBE			B.II.d.2.d B.II.d.2.d - QUALITY
+SIMVAST	+SIMVAST			CHANGES - FINISHED PRODUCT -
ATIN/MYLA	ATIN/MYLA			Control of finished product - Change in
N TABLET	N TABLET		MYLAN	test procedure for the finished product -
10MG/10M	10MG/10M		IRELAND	Other changes to a test procedure
G	G	4971/23T	LIMITED	(including replacement or addition)
				B.I.b.2.a B.I.b.2.a - QUALITY
				CHANGES - ACTIVE SUBSTANCE -
				Control of active substance - Change in test procedure for active substance or
				starting material/reagent/intermediate
				used in the manufacturing process of
				the active substance - Minor changes to
				an approved test procedure
				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
RAFAZIL	RAFAZIL			active substance, starting material,
ORAL	ORAL			reagent or intermediate used in the
SOLUTION	SOLUTION	2958/23T, 2959/23T,		manufacture of the active substance
1MG/1ML	1MG/1ML	2960/23T	RAFARM S.A.	(where specified in the technical doss
				B.I.b.1.c B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE -
				Control of active substance - Change in
				the specification parameters and/or
				limits of an active substance, starting
				material / intermediate / reagent used in
				the manufacturing process of the active
				substance - Addition of a new
	CLOPERAN		DEVEDION	specification parameter to the
TABLET	TABLET	0000/00T	REMEDICA	specification with its corresponding test
10MG	10MG	6330/23T	LTD	method C.I.z C.I.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
CLOPERAN	CLOPERAN			HUMAN AND VETERINARY
TABLET	TABLET		REMEDICA	MEDICINAL PRODUCTS - Other
10MG	10MG	6101/23T	LTD	variation
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
MOXILEN	MOXILEN			an active substance For a starting material/reagent/intermediate used in
FORTE	FORTE			the manufacturing process of the active
POWDER	POWDER			substance For an excipient - European
FOR ORAL	FOR ORAL			Pharmacopoeial Certificate of Suitability
SUSPENSI	SUSPENSI			to the relevant Ph. Eur. Monograph -
ON	ON		MEDOCHEMIE	Updated certificate from an already
250MG/5ML	250MG/5ML	5264/23T	LTD	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
MOXILEN	MOXILEN			CHANGES - CEP/TSE/MONOGRAPHS
POWDER FOR ORAL	POWDER FOR ORAL			- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
SUSPENSI	SUSPENSI			of Ph. Eur. certificate of suitability of deletion
ON	ON		MEDOCHEMIE	an active substance For a starting
125MG/5ML	125MG/5ML	5265/23T	LTD	material/reagent/intermediate used in

				the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already
FRUMIL TABLET	FRUMIL TABLET	776/22T	Sanofi Winthrop Industrie.	approved manufacturer 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
PRIMPERA N SOLUTION FOR INJECTION 10MG/2ML	PRIMPERA N 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, PROLONG ED- RELEASE 500MG	DEPAKINE CHRONO TABLET, PROLONG ED- 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 SUSPENSI ON	MAALOX PLUS ORAL SUSPENSI ON	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 SUSPENSI ON (22.8+40)M G/ML	MAALOX ORAL SUSPENSI ON (22.8+40)M G/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, CHEWABL E	MAALOX PLUS TABLET, CHEWABL E	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
MEDODEX AN SOLUTION FOR INJECTION OR	MEDODEX AN 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	DENEX			A.7 A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent
TABLET 100MG	TABLET 100MG	5136/23T, 5137/23T	MEDOCHEMIE LTD	or excipient (when mentioned in the dossier)*
PENTAXIM POWDER AND SUSPENSI ON FOR SUSPENSI ON FOR INJECTION	PENTAXIM POWDER AND SUSPENSI ON FOR SUSPENSI ON 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)
				B.II.d.2.a B.II.d.2.a - QUALITY
FLUNOL CAPSULE, HARD 100MG	FLUNOL CAPSULE, HARD 100MG	5169/23T	PHARMA Q AE	CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure
LEVOFLOX ACIN VIOSER SOLUTION FOR INFUSION 5MG/ML	LEVOFLOX ACIN 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 NEXTHALE R POWDER FOR INHALATIO N 100MCG/6 MCG	FOSTER NEXTHALE R POWDER FOR INHALATIO N 100MCG/6 MCG	4983/23T	CHIESI FARMACEUTI CI 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% STRAWBE RRY ORAL SUSPENSI ON 4%	NUROFEN FOR CHILDREN 4% STRAWBE RRY ORAL SUSPENSI ON 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 SUSPENSI ON 4%	NUROFEN FOR CHILDREN 4% ORANGE ORAL SUSPENSI ON 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
NUROFEN DURANCE MEDICATE D PLASTER 200MG	NUROFEN DURANCE MEDICATE D PLASTER 200MG	8805/22T	RECKITT BENCKISER HELLAS HEALTHCARE SA	upon C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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 OROMUCO SAL SPRAY 8.75MG	STREPFEN DIRECT CHERRY & MINT OROMUCO SAL 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 OROMUCO SAL SPRAY, SOLUTION 8.75MG	STREPFEN DIRECT HONEY & LEMON OROMUCO SAL 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

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				1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed
VERRIA TABLET, FILM COATED 50MG	VERRIA TABLET, FILM COATED 50MG	5097/23T	MEDOCHEMIE	upon C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment
VERRIA TABLET, FILM COATED 200MG	VERRIA TABLET, FILM COATED 200MG	5096/23T	MEDOCHEMIE	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of product 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	MUNDIPHARM A PHARMACEU TICALS 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
MACROGO L 4000 CASEN RECORDA TI POWDER FOR ORAL SOLUTION IN SACHET 4G	MACROGO L 4000 CASEN RECORDA TI 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
MACROGO L 4000 CASEN RECORDA TI POWDER FOR ORAL SOLUTION IN SACHET 10G	MACROGO L 4000 CASEN RECORDA TI 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
MACROGO L 4000 CASEN RECORDA TI POWDER FOR ORAL	MACROGO L 4000 CASEN RECORDA TI 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	SOLUTION			the manufacturing process of the active
IN SACHET 4G	IN SACHET 4G			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.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
MACROGO	MACROGO			- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
L 4000 CASEN	L 4000 CASEN			of Ph. Eur. certificate of suitability: For an active substance For a starting
RECORDA TI	RECORDA TI			material/reagent/intermediate used in the manufacturing process of the active
POWDER	POWDER			substance For an excipient - European
FOR ORAL SOLUTION	FOR ORAL SOLUTION		CASEN	Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph -
IN SACHET 10G	IN SACHET 10G	1820/23T, 1821/23T	RECORDATI SL	Updated certificate from an already approved manufacturer
				C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
	LYBEREN			medicinal products following
LYBEREN TABLET,	TABLET,			assessment of the same change for the reference product - Implementation of
FILM COATED	FILM COATED		ELPEN PHARMACEU	change(s) for which no new additional data is required to be submitted by the
1000MG	1000MG	5196/23T	TICAL CO INC	MAH C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar medicinal products following
				assessment of the same change for the
TABLET, FILM	TABLET, FILM		ELPEN	reference product - Implementation of change(s) for which no new additional
COATED 250MG	COATED 250MG	5199/23T	PHARMACEU TICAL CO INC	data is required to be submitted by the MAH
				C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar
LYBEREN	LYBEREN			medicinal products following assessment of the same change for the
TABLET, FILM	TABLET, FILM		ELPEN	reference product - Implementation of change(s) for which no new additional
COATED	COATED	- 4 07/00 7	PHARMACEU	data is required to be submitted by the
750MG	750MG	5197/23T	TICAL CO INC	MAH C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package
LYBEREN TABLET,	LYBEREN TABLET,			Leaflet of a generic/hybrid/biosimilar medicinal products following
FILM COATED	FILM COATED		ELPEN PHARMACEU	assessment of the same change for the reference product - Implementation of
500MG	500MG	5198/23T	TICAL CO INC	change(s) for which no new additional

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				data is required to be submitted by the MAH
TICEVIS TABLET 10MG	TICEVIS TABLET 10MG	5200/23T	MEDOCHEMIE	C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the 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 SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 60MCG/DO SE	EFLUELDA SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE 60MCG/DO SE	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
AGGRAST AT CONCENT RATE FOR SOLUTION FOR INFUSION 0.25MG/ML	AGGRAST AT CONCENT RATE 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
				C.I.2.a C.I.2.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar
				medicinal products following
				assessment of the same change for the reference product - Implementation of
KRATIUM	KRATIUM			change(s) for which no new additional
TABLET	TABLET		MEDOCHEMIE	data is required to be submitted by the
2MG	2MG	4182/23T	LTD	МАН
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
SORIL-	SORIL-			material/reagent/intermediate used in the manufacturing process of the active
MED	MED			substance For an excipient - European
ORANGE	ORANGE			Pharmacopoeial Certificate of Suitability
LOZENGE	LOZENGE		SAPIENS	to the relevant Ph. Eur. Monograph -
2MG/0.60M	2MG/0.60M	5405/00T	PHARMACEU	Updated certificate from an already
G/1.20MG	G/1.20MG	5125/23T	TICALS LTD	approved manufacturer C.I.5.z C.I.5.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change in
TABLET, COATED	TABLET, COATED		REMEDICA	the legal status of a medicinal product for centrally authorised products - Other
10MG	10MG	5029/23T	LTD	variation
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
AXETINE	AXETINE			Leaflet of human medicinal products
POWDER FOR	POWDER FOR			intended to implement the outcome of a procedure concerning PSUR or PASS,
SOLUTION	SOLUTION			or the outcome of the assessment done
FOR	FOR			by the competent authority under
INJECTION	INJECTION			Articles 45 or 46 of Regulation
/INFUSION 1.5G	/INFUSION 1.5G	3592/23T	MEDOCHEMIE LTD	1901/2006 - Implementation of wording
1.50	1.50	3332/231		agreed by the competent authority C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
AXETINE	AXETINE			in the Summary of Product Characteristics, Labelling or Package
POWDER	POWDER			Leaflet of human medicinal products
FOR	FOR			intended to implement the outcome of a
SOLUTION	SOLUTION			procedure concerning PSUR or PASS,
FOR INJECTION	FOR INJECTION			or the outcome of the assessment done by the competent authority under
/INFUSION	/INFUSION			Articles 45 or 46 of Regulation
250MG/VIA	250MG/VIA		MEDOCHEMIE	1901/2006 - Implementation of wording
L	L	3590/23T	LTD	agreed by the competent authority

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AXETINE POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG/VIA L	AXETINE POWDER FOR SOLUTION FOR INJECTION /INFUSION 750MG/VIA L	3591/23T	MEDOCHEMIE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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/VIA L	AXETINE POWDER FOR SOLUTION FOR INJECTION /INFUSION 250MG/VIA L	null	MEDOCHEMIE	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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 INFUSION 10MG/ML	VINORELBI NE ACCORD CONCENT RATE 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 PERITONE AL DIALYSIS 1.25MMOL/ L CALCIUM, 1.5% GLUCOSE	BICAVERA SOLUTION FOR PERITONE AL DIALYSIS 1.25MMOL/ L CALCIUM, 1.5% GLUCOSE	131/23T	FRESENIUS MEDICAL CARE DEUTSCHLAN D GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
BICAVERA SOLUTION FOR PERITONE AL DIALYSIS 1.25MMOL/ L CALCIUM, 2.3% GLUCOSE BICAVERA SOLUTION FOR PERITONE AL DIALYSIS	BICAVERA SOLUTION FOR PERITONE AL DIALYSIS 1.25MMOL/ L CALCIUM, 2.3% GLUCOSE BICAVERA SOLUTION FOR PERITONE AL DIALYSIS	130/23T 129/23T	FRESENIUS MEDICAL CARE DEUTSCHLAN D GMBH FRESENIUS MEDICAL CARE DEUTSCHLAN D GMBH	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation

1.25MMOL/				
L	1.25MMOL/ L			
CALCIUM,	CALCIUM,			
4.25%	4.25%			
GLUCOSE	GLUCOSE			
LIOTON 1000 GEL 100000IU/1 00G	LIOTON 1000 GEL 100000IU/1 00G	5046/23T	A. MENARINI INDUSTRIE FARMACEUTI CHE 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)*
				B.III.1.a.2 B.III.1.a.2 - QUALITY
PULMICOR T NEBULISE R SUSPENSI ON 0.25MG/ML	PULMICOR T NEBULISE R SUSPENSI ON 0.25MG/ML	5017/23T, 5018/23T, 5019/23T	ASTRAZENEC A AB	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY
PULMICOR T NEBULISE R SUSPENSI ON 0.5MG/ML	PULMICOR T NEBULISE R SUSPENSI ON 0.5MG/ML	5014/23T, 5015/23T, 5016/23T	ASTRAZENEC A AB	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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
VENLAXIN TABLET, PROLONG ED- RELEASE 225MG VENLAXIN TABLET,	VENLAXIN TABLET, PROLONG ED- RELEASE 225MG VENLAXIN TABLET,	4985/23T, 4986/23T	IASIS PHARMACEU TICALS HELLAS SA IASIS	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active 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 B.III.1.a.3 B.III.1.a.3 - QUALITY
TABLET,	TABLET, PROLONG	1087/23T 1000/22T	IASIS PHARMACEU	CHANGES - CEP/TSE/MONOGRAPHS
PROLONG	FRULUNG	4987/23T, 4988/23T		- Submission of a new or updated Ph.

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

				and distant and death following
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)
				B.II.b.3.a B.II.b.3.a - QUALITY
				CHANGES - FINISHED PRODUCT -
LIPIDIL NT	LIPIDIL NT			Manufacture - Change in the manufacturing process of the finished
TABLET,	TABLET,			product, including an intermediate used
FILM COATED	FILM COATED		VIATRIS HEALTHCARE	in the manufacture of the finished product - Minor change in the
145MG	145MG	4887/23T	LIMITED.	manufacturing process
EPIDUO FORTE	EPIDUO FORTE		GALDERMA	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
GEL	GEL		INTERNATION	and/or address of the marketing
0.3%/2.5% MEDOPRA	0.3%/2.5% MEDOPRA	4788/23T	AL,FRANCE	authorisation holder
ZOLE	ZOLE			C.I.5.z C.I.5.z - SAFETY, EFFICACY,
GASTRO-	GASTRO-			PHARMACOVIGILANCE CHANGES -
RESISTAN T	RESISTAN T			HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in
CAPSULE,	CAPSULE,			the legal status of a medicinal product
HARD 20MG	HARD 20MG	5227/23T	MEDOCHEMIE LTD	for centrally authorised products - Other variation
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
			OPELLA	material/reagent/intermediate used in
			HEALTHCARE	the manufacturing process of the active
MUCOSOL	MUCOSOL		GREECE	substance For an excipient - European Pharmacopoeial Certificate of Suitability
VAN	VAN		MEMBER LTD	to the relevant Ph. Eur. Monograph -
SYRUP 15MG/5ML	SYRUP 15MG/5ML	4773/23T	(OPELLA E.P.E.)	Updated certificate from an already approved manufacturer
			,	B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For an active substance For a starting
			OPELLA	material/reagent/intermediate used in
			HEALTHCARE	the manufacturing process of the active
MUCOSOL	MUCOSOL		GREECE SINGLE	substance For an excipient - European Pharmacopoeial Certificate of Suitability
VAN	VAN		MEMBER LTD	to the relevant Ph. Eur. Monograph -
SYRUP 30MG/5ML	SYRUP 30MG/5ML	4772/23T	(OPELLA E.P.E.)	Updated certificate from an already approved manufacturer
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a procedure concerning PSUR or PASS,
				or the outcome of the assessment done
ZETIVASIM	ZETIVASIM			by the competent authority under
TABLET 10MG/80M	TABLET 10MG/80M		ANFARM	Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
G	G	3022/23T	HELLAS S.A.	agreed by the competent authority
ZETIVASIM	ZETIVASIM		ANFARM	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
TABLET	TABLET	3024/23T	HELLAS S.A.	HUMAN AND VETERINARY

40140/0014	40140/0014	1		
10MG/20M G	10MG/20M G			MEDICINAL PRODUCTS - Change(s) in the Summary of Product
9	9			Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of 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.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of the assessment done
ZETIVASIM	ZETIVASIM			by the competent authority under
TABLET	TABLET			Articles 45 or 46 of Regulation
10MG/40M	10MG/40M		ANFARM	1901/2006 - Implementation of wording
G	G	3023/23T	HELLAS S.A.	agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
				or the outcome of the assessment done
ZETIVASIM TABLET	ZETIVASIM TABLET			by the competent authority under Articles 45 or 46 of Regulation
10MG/10M	10MG/10M		ANFARM	1901/2006 - Implementation of wording
G	G	3025/23T	HELLAS S.A.	agreed by the competent authority
	<u> </u>	0020/201	TIELE/ (0 0./ (.	B.II.d.1.z B.II.d.1.z - QUALITY
				CHANGES - FINISHED PRODUCT -
				Control of finished product - Change in
AZOLAM	AZOLAM		SAPIENS	the specification parameters and/or
TABLET	TABLET		PHARMACEU	limits of the finished product - Other
0.5MG	0.5MG	5727/23T	TICALS LTD	changes
				B.II.d.1.z B.II.d.1.z - QUALITY
				CHANGES - FINISHED PRODUCT -
				Control of finished product - Change in
AZOLAM	AZOLAM		SAPIENS	the specification parameters and/or
TABLET	TABLET	5700/007	PHARMACEU	limits of the finished product - Other
0.25MG	0.25MG	5728/23T	TICALS LTD	changes
				B.II.d.1.z B.II.d.1.z - QUALITY
				CHANGES - FINISHED PRODUCT -
AZOLAM	AZOLAM		SAPIENS	Control of finished product - Change in the specification parameters and/or
TABLET	TABLET		PHARMACEU	limits of the finished product - Other
1MG	1MG	5726/23T	TICALS LTD	changes
DIOVAN	DIOVAN			
ORAL	ORAL		NOVARTIS	A.3 A.3 - ADMINISTRATIVE
SOLUTION	SOLUTION		IRELAND	CHANGES - Change in name of the
3MG/ML	3MG/ML	2822/23T	LIMITED	active substance or of an excipient
				C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
ATODEL	ATODEL			Leaflet of human medicinal products
TABLET	TABLET		REMEDICA	intended to implement the outcome of a
2MG	2MG	5777/23T	LTD	procedure concerning PSUR or PASS,

	1	•	1	
				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	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure 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	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure 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 PHARMACEU TICAL 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: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active 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
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

	1		1	
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				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
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
				Dharmanaan a int Cartificate of Cuitability
				Pharmacopoeial Certificate of Suitability
AMLOBE	AMLOBE			to the relevant Ph. Eur. Monograph
TABLET	TABLET		TAD PHARMA	to the relevant Ph. Eur. Monograph New certificate from a new
-	-	5660/23T, 5661/23T	TAD PHARMA GMBH	to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (replacement or addition)
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (replacement or addition) B.II.d.1.h B.II.d.1.h - QUALITY
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (replacement or addition) B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT -
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (replacement or addition) B.II.d.1.h B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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*
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.2.d B.II.d.2.d - QUALITY
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.2.d B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product -
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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)
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 -
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - Other 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
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 -
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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.
TABLET	TABLET	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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
TABLET 5MG	TABLET 5MG	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - 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
TABLET 5MG METRONID	TABLET 5MG	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - 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*
TABLET 5MG METRONID AZOLE	TABLET 5MG METRONID AZOLE	5660/23T, 5661/23T		to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - 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
TABLET 5MG METRONID AZOLE B.BRAUN	METRONID AZOLE B.BRAUN			to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - 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 -
TABLET 5MG METRONID AZOLE B.BRAUN SOLUTION	METRONID AZOLE B.BRAUN SOLUTION	2878/23T, 2879/23T,	GMBH	to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - 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
TABLET 5MG METRONID AZOLE B.BRAUN SOLUTION FOR	METRONID AZOLE B.BRAUN SOLUTION FOR	2878/23T, 2879/23T, 2880/23T, 2881/23T,	GMBH B. BRAUN	to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - To reflect compliance with the Ph.Eur.
TABLET 5MG METRONID AZOLE B.BRAUN SOLUTION FOR INFUSION	METRONID AZOLE B.BRAUN SOLUTION FOR INFUSION	2878/23T, 2879/23T, 2880/23T, 2881/23T, 2882/23T, 2883/23T,	GMBH B. BRAUN MELSUNGEN	to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - 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 - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test
TABLET 5MG METRONID AZOLE B.BRAUN SOLUTION FOR INFUSION 5MG/ML	METRONID AZOLE B.BRAUN SOLUTION FOR INFUSION 5MG/ML	2878/23T, 2879/23T, 2880/23T, 2881/23T,	GMBH B. BRAUN	to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - 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
TABLET 5MG METRONID AZOLE B.BRAUN SOLUTION FOR INFUSION	METRONID AZOLE B.BRAUN SOLUTION FOR INFUSION	2878/23T, 2879/23T, 2880/23T, 2881/23T, 2882/23T, 2883/23T,	B. BRAUN MELSUNGEN AG	to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - 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 B.II.e.7.b B.II.e.7.b - QUALITY
METRONID AZOLE B.BRAUN SOLUTION FOR INFUSION 5MG/ML METRONID	METRONID AZOLE B.BRAUN SOLUTION FOR INFUSION 5MG/ML METRONID	2878/23T, 2879/23T, 2880/23T, 2881/23T, 2882/23T, 2883/23T,	GMBH B. BRAUN MELSUNGEN	to the relevant Ph. Eur. Monograph New certificate from a new manufacturer (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.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 - 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

SOLUTION FOR	SOLUTION FOR		SOLUTIONS	supplier of packaging components or devices (when mentioned in the dossier)
INFUSION 500MG/100	INFUSION		INDUSTRI	- Replacement or addition of a supplier
ML	500MG/100 ML			
SANDIMMU N NEORAL CAPSULE, SOFT 100MG	SANDIMMU N 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
SANDIMMU N NEORAL CAPSULE, SOFT 25MG	SANDIMMU N 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
SANDIMMU N NEORAL CAPSULE, SOFT 50MG	SANDIMMU N 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
SANDIMMU N NEORAL ORAL SOLUTION 100MG/ML	SANDIMMU N 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
CISATRAC URIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 2MG/ML	CISATRAC URIUM 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)
CISATRAC URIUM ACCORD SOLUTION FOR INJECTION OR INFUSION 5MG/ML	CISATRAC URIUM 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)
ATORVAST ATIN SANDOZ TABLET, FILM COATED 40MG ATORVAST	ATORVAST ATIN SANDOZ TABLET, FILM COATED 40MG ATORVAST	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
ATORVAST ATIN SANDOZ TABLET, FILM COATED 10MG	ATORVAST ATIN 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

ATORVAST ATIN SANDOZ TABLET, FILM COATED 20MG	ATORVAST ATIN 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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
SUGAMMA DEX ANABIOSIS SOLUTION FOR INJECTION 100MG/ML	SUGAMMA DEX 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
MYCOPHE NOLIC ACID ACCORD TABLET, GASTRO- RESISTAN T 360MG	MYCOPHE NOLIC ACID ACCORD TABLET, GASTRO- RESISTAN T 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
MYCOPHE NOLIC ACID ACCORD TABLET, GASTRO- RESISTAN T 180MG	MYCOPHE NOLIC ACID ACCORD TABLET, GASTRO- RESISTAN T 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 PHARMACEU TICALS 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

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				manufacturer responsible for importation and/or batch release - Not
				including batch control/testing
				A.7 A.7 - ADMINISTRATIVE
				CHANGES - Deletion of manufacturing sites for an active substance,
				intermediate or finished product,
				packaging site, manufacturer
				responsible for batch release, site
				where batch control takes place, or
				supplier of a starting material, reagent or excipient (when mentioned in the
				dossier)*
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
BETASERC	BETASERC		VIATRIS	to the relevant Ph. Eur. Monograph
TABLET	TABLET		HEALTHCARE	New certificate from a new
16MG	16MG	5223/23T, 5224/23T	LIMITED.	manufacturer (replacement or addition)
				A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
				and/or address of a
				manufacturer/importer of the 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
TOPIRAMA				- Deletion of manufacturing sites for an
TE	TOPIRAMA TE			active substance, intermediate or finished product, packaging site,
AUROBIND	AUROBIND			manufacturer responsible for batch
O TABLET,	O TABLET,		AUROBINDO	release, site where batch control takes
FILM	FILM			place, or supplier of a starting material,
COATED 50MG	COATED 50MG	4015/23T, 4016/23T	(MALTA) LIMITED	reagent or excipient (when mentioned in the dossier)*
00000	00000	4010/201, 4010/201		A.5.b A.5.b - ADMINISTRATIVE
				CHANGES - Change in the name
				and/or address of a
				manufacturer/importer of the 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
TOPIRAMA	TOPIRAMA			active substance, intermediate or
TE	TE			finished product, packaging site,
AUROBIND O TABLET,	AUROBIND O TABLET,		AUROBINDO	manufacturer responsible for batch release, site where batch control takes
FILM	FILM		PHARMA	place, or supplier of a starting material,
COATED	COATED		(MALTA)	reagent or excipient (when mentioned in
100MG	100MG	4013/23T, 4014/23T	LIMITED	the dossier)*
TOPIRAMA	TOPIRAMA			A.5.b A.5.b - ADMINISTRATIVE CHANGES - Change in the name
TE	TE			and/or address of a
AUROBIND	AUROBIND			manufacturer/importer of the finished
O TABLET,	O TABLET,		AUROBINDO	product (including batch release or
FILM COATED	FILM COATED		PHARMA (MALTA)	quality control testing sites) - The activities for which the
25MG	25MG	4017/23T, 4018/23T	LIMITED	manufacturer/importer is responsible do
<u> </u>		, , , , , , , , , , , , , , , , , , , ,	-	

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				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)*
TOPIRAMA TE AUROBIND O TABLET, FILM COATED 200MG	TOPIRAMA TE AUROBIND O 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- RESISTAN T 20MG	REPRAT TABLET, GASTRO- RESISTAN T 20MG	5424/23T	DELORBIS PHARMACEU TICALS 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
RISPERIDO NE- REMEDICA TABLET, FILM COATED 1MG	RISPERIDO NE- 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
RISPERIDO NE- REMEDICA TABLET, FILM COATED 2MG	RISPERIDO NE- 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
RISPERIDO NE- REMEDICA TABLET, FILM COATED 4MG	RISPERIDO NE- 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
RISPERIDO NE- REMEDICA TABLET, FILM COATED 6MG	RISPERIDO NE- 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
RISPERIDO NE- REMEDICA TABLET, FILM COATED 3MG	RISPERIDO NE- 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)*
SEDISTRE SS TABLET, COATED 200MC	SEDISTRE SS TABLET, COATED 200MG	4872/22T 4874/22T	TH MAN 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
200MG	200MG	4873/23T, 4874/23T	TILMAN S.A.	batch control/testing takes place
REPRAT TABLET, GASTRO- RESISTAN T 40MG	REPRAT TABLET, GASTRO- RESISTAN T 40MG	4937/23T, 4938/23T	DELORBIS PHARMACEU TICALS 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- RESISTAN T 20MG	REPRAT TABLET, GASTRO- RESISTAN T 20MG OXIMEZIN	4939/23T, 4940/23T	DELORBIS PHARMACEU TICALS 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	POWDER FOR SOLUTION FOR INJECTION /INFUSION 2G/VIAL	3148/23T	NORIDEM ENTERPRISE S 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 ENTERPRISE S 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 ENTERPRISE S 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
POTASSIU M IODIDE G.L.PHARM A TABLET 65MG	POTASSIU M IODIDE G.L.PHARM A 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)M G/15ML	LEGOFER ORAL SOLUTION 800(40Fe)M G/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)
RANOLAZI NE ELC TABLET, PROLONG ED- RELEASE 375MG	RANOLAZI NE ELC TABLET, PROLONG ED- 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
RANOLAZI NE ELC TABLET, PROLONG ED- RELEASE 500MG	RANOLAZI NE ELC TABLET, PROLONG ED- 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 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
					manufacture 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,
RAN	OLAZI	RANOLAZI			reagent or intermediate use B.I.a.3.a B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE -
NE E TABL	.ET,	NE ELC TABLET,			Manufacture - Change in batch size (including batch size ranges) of active
ED-	LONG	PROLONG ED- RELEASE	4113/23T, 4114/23T, 4115/23T, 4116/23T,	ELC GROUP	substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase
750M	-	750MG	4117/23T, 4118/23T	S.R.O.	compare A.7 A.7 - ADMINISTRATIVE
					CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product,
					packaging site, manufacturer 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
ARIP OLE	IPRAZ	ARIPIPRAZ OLE		AUROBINDO	manufacturer/importer of the finished product (including batch release or quality control testing sites) - The
AURO O TA	OBIND BLET	AUROBIND O TABLET		PHARMA (MALTA)	activities for which the manufacturer/importer is responsible do
10MC	3	10MG	3989/23T, 3990/23T	LIMITED	not include batch release

ARIPIPRAZ OLE AUROBIND O TABLET 15MG	ARIPIPRAZ OLE AUROBIND O 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
ARIPIPRAZ OLE AUROBIND O TABLET 30MG	ARIPIPRAZ OLE AUROBIND O 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	GLAXOSMITH KLINE (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	GLAXOSMITH KLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

LAMICTAL	LAMICTAL			
TABLET,	TABLET,			
CHEWABL	CHEWABL		GLAXOSMITH	A.1 A.1 - ADMINISTRATIVE
E/				CHANGES - Change in the name
DISPERSIB		5144/00T	(IRELAND)	and/or address of the marketing
LE 200MG	LE 200MG	5144/23T	LIMITED	authorisation holder
LAMICTAL TABLET,	LAMICTAL TABLET,			
CHEWABL	CHEWABL		GLAXOSMITH	A.1 A.1 - ADMINISTRATIVE
	E/		KLINE	CHANGES - Change in the name
DISPERSIB	DISPERSIB		(IRELAND)	and/or address of the marketing
LE 25MG	LE 25MG	5141/23T		authorisation holder
LAMICTAL	LAMICTAL	0111/201		
TABLET,	TABLET,			
CHEWABL	CHEWABL		GLAXOSMITH	A.1 A.1 - ADMINISTRATIVE
E/	E/		KLINE	CHANGES - Change in the name
DISPERSIB	DISPERSIB		(IRELAND)	and/or address of the marketing
LE 100MG	LE 100MG	5139/23T	LIMITED	authorisation holder
LAMICTAL	LAMICTAL			
TABLET,	TABLET,			
CHEWABL	CHEWABL		GLAXOSMITH	A.1 A.1 - ADMINISTRATIVE
E/	E/		KLINE	CHANGES - Change in the name
DISPERSIB	DISPERSIB		(IRELAND)	and/or address of the marketing
LE 50MG	LE 50MG	5140/23T	LIMITED	authorisation holder
			GLAXOSMITH	
INDOXYL	INDOXYL		KLINE	A.1 A.1 - ADMINISTRATIVE
GEL	GEL		TRADING	CHANGES - Change in the name
10MG/G+50	10MG/G+50		SERVICES	and/or address of the marketing
MG/G	MG/G	5145/23T	LIMITED.	authorisation holder
FLUARIX	FLUARIX			
TETRA	TETRA			
SUSPENSI	SUSPENSI			
ON FOR	ON FOR		GLAXOSMITH	A.1 A.1 - ADMINISTRATIVE
INJECTION	INJECTION		KLINE	CHANGES - Change in the name
15MCG/0.5	15MCG/0.5		BIOLOGICALS	and/or address of the marketing
10100/0.0			DIOLOGICALS	anu/or address of the marketing
ML	ML	5150/23T	SA	authorisation holder
ML SERETIDE	ML SERETIDE	5150/23T		
ML SERETIDE DISKUS	ML SERETIDE DISKUS	5150/23T		
ML SERETIDE DISKUS INHALATIO	ML SERETIDE DISKUS INHALATIO	5150/23T		
ML SERETIDE DISKUS INHALATIO N	ML SERETIDE DISKUS INHALATIO N	5150/23T		
ML SERETIDE DISKUS INHALATIO N POWDER,	ML SERETIDE DISKUS INHALATIO N POWDER,	5150/23T	SA	
ML SERETIDE DISKUS INHALATIO N POWDER, PRE-	ML SERETIDE DISKUS INHALATIO N POWDER, PRE-	5150/23T	GLAXOSMITH	authorisation holder
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE	5150/23T	SA GLAXOSMITH KLINE	A.1 A.1 - ADMINISTRATIVE
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D	5150/23T	SA GLAXOSMITH KLINE TRADING	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100		SA GLAXOSMITH KLINE TRADING SERVICES	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG	5150/23T 5148/23T	SA GLAXOSMITH KLINE TRADING	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL		SA GLAXOSMITH KLINE TRADING SERVICES	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET,	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET,		SA GLAXOSMITH KLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL		SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E /	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E /		SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB	5148/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG		SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL	5148/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET,	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET,	5148/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL	5148/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E /	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E /	5148/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE GLAXOSMITH KLINE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB	5148/23T 5142/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG	5148/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE GLAXOSMITH KLINE	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE	5148/23T 5142/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS	5148/23T 5142/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE	5148/23T 5142/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N	5148/23T 5142/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO	5148/23T 5142/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND)	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER,	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER,	5148/23T 5142/23T	SA GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER, PRE-	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER, PRE-	5148/23T 5142/23T	GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE	5148/23T 5142/23T	GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D	5148/23T 5142/23T	GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND) LIMITED	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/250 MCG SERETIDE	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/250	5148/23T 5142/23T 5143/23T 5147/23T	GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE TRADING SERVICES	authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder
ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/250 MCG	ML SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/100 MCG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 5MG LAMICTAL TABLET, CHEWABL E / DISPERSIB LE 2MG SERETIDE DISKUS INHALATIO N POWDER, PRE- DISPENSE D 50MCG/250 MCG	5148/23T 5142/23T 5143/23T	GLAXOSMITH KLINE TRADING SERVICES LIMITED. GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE (IRELAND) LIMITED GLAXOSMITH KLINE TRADING SERVICES LIMITED.	A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder A.1 A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder

INHALATIO	INHALATIO		TRADING	and/or address of the marketing
N	N		SERVICES	authorisation holder
POWDER, PRE-	POWDER, PRE-		LIMITED.	
DISPENSE	DISPENSE			
D	D			
50MCG/500	50MCG/500			
MCG	MCG			
NETAXAN	NETAXAN			
EYE	EYE			
DROPS,	DROPS,			
SOLUTION	SOLUTION			B.II.d.1.e B.II.d.1.e - QUALITY
IN SINGLE-	IN SINGLE-			CHANGES - FINISHED PRODUCT -
DOSE	DOSE			Control of finished product - Change in
CONTAINE R	CONTAINE R			the specification parameters and/or limits of the finished product - Change
(3MG/1MG)	(3MG/1MG)			outside the approved specifications
/ML	/ML	8764/22T	SIFI S.P.A	limits range
,	,			B.II.d.1.e B.II.d.1.e - QUALITY
NETAXAN	NETAXAN			CHANGES - FINISHED PRODUCT -
EYE	EYE			Control of finished product - Change in
DROPS,	DROPS,			the specification parameters and/or
SOLUTION	SOLUTION			limits of the finished product - Change
(3MG/1MG)	(3MG/1MG)	0705/00T		outside the approved specifications
/ML	/ML	8765/22T	SIFI S.P.A	limits range B.III.1.a.2 B.III.1.a.2 - QUALITY
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
	DEDMOVA			substance For an excipient - European
DERMOVA TE	DERMOVA TE		GLAXOSMITH KLINE	Pharmacopoeial Certificate of Suitability
			(IRELAND)	to the relevant Ph. Eur. Monograph - Updated certificate from an already
0.05% W/W	0.05% W/W	4769/23T		approved manufacturer
0.0070 10710	0.00 /0 10/10	1100/201		B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active substance For an excipient - European
			GLAXOSMITH	Pharmacopoeial Certificate of Suitability
DERMOVA	DERMOVA		KLINE	to the relevant Ph. Eur. Monograph -
TE CREAM	TE CREAM		(IRELAND)	Updated certificate from an already
0.05% W/W	0.05% W/W	4770/23T	LIMITED	approved manufacturer
MACROGO	MACROGO			A.7 A.7 - ADMINISTRATIVE
L 4000	L 4000			CHANGES - Deletion of manufacturing
CASEN				sites for an active substance,
RECORDA TI	RECORDA TI			intermediate or finished product, packaging site, manufacturer
POWDER	POWDER			responsible for batch release, site
FOR ORAL	FOR ORAL			where batch control takes place, or
SOLUTION	SOLUTION		CASEN	supplier of a starting material, reagent
IN SACHET	IN SACHET		RECORDATI	or excipient (when mentioned in the
10G	10G	1393/23T	SL	dossier)*
MACROGO	MACROGO			A.7 A.7 - ADMINISTRATIVE
L 4000	L 4000			CHANGES - Deletion of manufacturing
				sites for an active substance,
RECORDA TI	RECORDA TI			intermediate or finished product, packaging site, manufacturer
POWDER	POWDER		CASEN	responsible for batch release, site
FOR ORAL	FOR ORAL		RECORDATI	where batch control takes place, or
SOLUTION	SOLUTION	1380/23T	SL	supplier of a starting material, reagent

IN SACHET	IN SACHET			or excipient (when mentioned in the
4G	4G			dossier)*
CLOPIDOG REL ACCORD TABLET, FILM COATED 75MG	CLOPIDOG REL 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
GENEMEN T TABLET, FILM COATED 20MG	GENEMEN T TABLET, FILM COATED 20MG	335/21T	SAPIENS PHARMACEU TICALS 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
GENEMEN T TABLET, FILM COATED 5MG	GENEMEN T TABLET, FILM COATED 5MG	334/21T	SAPIENS PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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

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				Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
				agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
ROTEQ	ROTEQ			procedure concerning PSUR or PASS, or the outcome of the assessment done
TABLET,	TABLET,			by the competent authority under
FILM	FILM		DELORBIS	Articles 45 or 46 of Regulation
COATED	COATED		PHARMACEU	1901/2006 - Implementation of wording
1MG	1MG	4807/23T	TICALS LTD	agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
ROTEQ	ROTEQ			or the outcome of the assessment done
TABLET,	TABLET,			by the competent authority under
FILM	FILM		DELORBIS	Articles 45 or 46 of Regulation
COATED	COATED		PHARMACEU	1901/2006 - Implementation of wording
2MG	2MG	4806/23T	TICALS LTD	agreed by the competent authority
				B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
CANDESA	CANDESA			an active substance For a starting
RTAN/HYD	RTAN/HYD			material/reagent/intermediate used in
ROCHLOR	ROCHLOR			the manufacturing process of the active
OTHIAZIDE	OTHIAZIDE			substance For an excipient - European Pharmacopoeial Certificate of Suitability
KRKA TABLET	KRKA TABLET			to the relevant Ph. Eur. Monograph -
8MG/12.5M	8MG/12.5M		KRKA D.D.	Updated certificate from an already
G	G	2624/23T	NOVO MESTO	approved manufacturer
-				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
CANDESA RTAN/HYD	CANDESA RTAN/HYD			an active substance For a starting material/reagent/intermediate used in
ROCHLOR	ROCHLOR			the manufacturing process of the active
OTHIAZIDE	OTHIAZIDE			substance For an excipient - European
KRKA	KRKA			Pharmacopoeial Certificate of Suitability
TABLET	TABLET			to the relevant Ph. Eur. Monograph -
16MG/12.5	16MG/12.5		KRKA D.D.	Updated certificate from an already
MG	MG	2623/23T	NOVO MESTO	approved manufacturer
				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
CANDESA	CANDESA			an active substance For a starting
RTAN/HYD	RTAN/HYD			material/reagent/intermediate used in
ROCHLOR	ROCHLOR			the manufacturing process of the active
OTHIAZIDE	OTHIAZIDE			substance For an excipient - European
KRKA	KRKA			Pharmacopoeial Certificate of Suitability
TABLET 32MG/25M	TABLET		KRKA D.D.	to the relevant Ph. Eur. Monograph -
32101G/25101 G	32MG/25M G	2621/23T	NOVO MESTO	Updated certificate from an already approved manufacturer
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CANDESA RTAN/HYD ROCHLOR OTHIAZIDE KRKA TABLET 32MG/12.5 MG	CANDESA RTAN/HYD ROCHLOR OTHIAZIDE 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 A.5.b A.5.b - ADMINISTRATIVE
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	CHANGES - Change in the name and/or address of a manufacturer/importer of the 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- RESISTAN T 5MG	DULCOLAX TABLET, GASTRO- RESISTAN T 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	C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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

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				intended to implement the outcome of a procedure concerning PSUR or PASS,
				or the outcome of 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.a C.I.3.a - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s) in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure concerning PSUR or PASS,
MEDOQUIP TABLET,	MEDOQUIP TABLET,			or the outcome of the assessment done by the competent authority under
FILM	FILM			Articles 45 or 46 of Regulation
COATED	COATED		MEDOCHEMIE	1901/2006 - Implementation of wording
2MG	2MG	5010/23T	LTD	agreed by the competent authority
				C.I.3.a C.I.3.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products intended to implement the outcome of a
				procedure concerning PSUR or PASS,
MEDOQUIP	MEDOQUIP			or the outcome of the assessment done
TABLET,	TABLET,			by the competent authority under
FILM COATED	FILM COATED		MEDOCHEMIE	Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording
1MG	1MG	5011/23T	LTD	agreed by the competent authority
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
CIPROFLO	CIPROFLO			the manufacturing process of the active
X TABLET,	X TABLET,			substance For an excipient - European Pharmacopoeial Certificate of Suitability
FILM	FILM		SAPIENS	to the relevant Ph. Eur. Monograph
COATED	COATED		PHARMACEU	New certificate from a new
250MG	250MG	4572/23T	TICALS LTD	manufacturer (replacement or addition)
				B.III.1.a.3 B.III.1.a.3 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting material/reagent/intermediate used in
				the manufacturing process of the active
CIPROFLO	CIPROFLO			substance For an excipient - European
X TABLET,	X TABLET,			Pharmacopoeial Certificate of Suitability
FILM COATED	FILM COATED		SAPIENS PHARMACEU	to the relevant Ph. Eur. Monograph New certificate from a new
500MG	500MG	4571/23T	TICALS LTD	manufacturer (replacement or addition)
				B.III.1.a.3 B.III.1.a.3 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph. Eur. Certificate of suitability or deletion
CIPROFLO	CIPROFLO			of Ph. Eur. certificate of suitability: For
X TABLET,	X TABLET,			an active substance For a starting
FILM	FILM		SAPIENS	material/reagent/intermediate used in
COATED	COATED	4570/22T		the manufacturing process of the active
750MG	750MG	4570/23T	TICALS LTD	substance For an excipient - European

				Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph
				New certificate from a new manufacturer (replacement or addition)
METHOTR EXATE/PFI ZER TABLET 2.5MG ORIZAL PLUS TABLET, FILM	METHOTR EXATE/PFI ZER TABLET 2.5MG ORIZAL PLUS TABLET, FILM	1962/23T	PFIZER HELLAS AE MENARINI INTERNATION AL OPERATIONS	C.I.3.z C.I.3.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
COATED 40/5/25MG	COATED 40/5/25MG	3277/23T	LUXEMBOUR G SA	MEDICINAL PRODUCTS - Other variation
ORIZAL PLUS TABLET, FILM COATED 20/5/12.5M G ORIZAL	ORIZAL PLUS TABLET, FILM COATED 20/5/12.5M G ORIZAL	3280/23T	MENARINI INTERNATION AL OPERATIONS LUXEMBOUR G SA MENARINI	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
PLUS TABLET, FILM COATED 40/10/25MG	PLUS TABLET, FILM COATED 40/10/25MG	3276/23T	INTERNATION AL OPERATIONS LUXEMBOUR G SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
ORIZAL PLUS TABLET, FILM COATED 40/5/12.5M G	ORIZAL PLUS TABLET, FILM COATED 40/5/12.5M G	3279/23T	MENARINI INTERNATION AL OPERATIONS LUXEMBOUR G 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 INTERNATION AL OPERATIONS LUXEMBOUR G SA	C.I.z C.I.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation
HAVRIX ADULTS SUSPENSI ON FOR INJECTION 1440 ELISA UNIT/ML	HAVRIX ADULTS SUSPENSI ON FOR INJECTION 1440 ELISA UNIT/ML	1850/23T, 1851/23T, 1852/23T, 1853/23T, 1854/23T	GLAXOSMITH KLINE 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 SUSPENSI ON FOR INJECTION 720 ELISA UNIT/0.5ML	HAVRIX JUNIOR SUSPENSI ON FOR INJECTION 720 ELISA UNIT/0.5ML	1845/23T, 1846/23T, 1847/23T, 1848/23T, 1849/23T	GLAXOSMITH KLINE 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 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
ZITHROMA X POWDER FOR ORAL SUSPENSI ON 200MG/5ML	ZITHROMA X POWDER FOR ORAL SUSPENSI ON 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
ZITHROMA X POWDER FOR SOLUTION FOR INFUSION 500MG/VIA L	ZITHROMA X POWDER FOR SOLUTION FOR INFUSION 500MG/VIA L	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

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				Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
CANDEPR ESS COMP TABLET 8MG/12.5M G	CANDEPR ESS COMP TABLET 8MG/12.5M G	4754/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDEPR ESS COMP TABLET 16MG/12.5 MG	CANDEPR ESS COMP TABLET 16MG/12.5 MG	4753/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDEPR ESS TABLET 32MG	CANDEPR ESS TABLET 32MG	4749/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
CANDEPR ESS TABLET 8MG	CANDEPR ESS TABLET 8MG	4751/23T	SAPIENS PHARMACEU TICALS LTD	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability ror an active substance For a starting material/reagent/intermediate used in
CANDEPR ESS TABLET 4MG CANDEPR ESS	CANDEPR ESS TABLET 4MG CANDEPR ESS	4752/23T 4750/23T	SAPIENS PHARMACEU TICALS LTD SAPIENS PHARMACEU TICALS LTD	the manufacturing process of 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.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph.

TABLET	TABLET			Eur. Certificate of suitability or deletion
16MG	16MG			of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
				the manufacturing process of the active
				substance For an excipient - European
				Pharmacopoeial Certificate of Suitability
				to the relevant Ph. Eur. Monograph -
				Updated certificate from an already
				approved manufacturer
				B.II.b.3.a B.II.b.3.a - QUALITY
				CHANGES - FINISHED PRODUCT -
VIDELMET TABLET,	VIDELMET TABLET,			Manufacture - Change in the manufacturing process of the finished
FILM	FILM			product, including an intermediate used
COATED	COATED		DELORBIS	in the manufacture of the finished
50MG/1000	50MG/1000		PHARMACEU	product - Minor change in the
MG	MG	3094/23T	TICALS LTD	manufacturing process
				B.II.b.3.a B.II.b.3.a - QUALITY
				CHANGES - FINISHED PRODUCT -
VIDELMET	VIDELMET			Manufacture - Change in the
TABLET,	TABLET,			manufacturing process of the finished
FILM	FILM			product, including an intermediate used
COATED	COATED		DELORBIS	in the manufacture of the finished
50MG/850M	50MG/850M	2005/227	PHARMACEU	product - Minor change in the
G	G	3095/23T	TICALS LTD	manufacturing process 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
SMOFKABI	SMOFKABI			CHANGES - FINISHED PRODUCT -
VEN PERIPHER	VEN PERIPHER			Stability - Change in the shelf-life or
AL	AL		FRESENIUS	storage conditions of the finished product - Extension of the shelf life of
EMULSION	EMULSION		KABI HELLAS	the finished product - After dilution or
FOR	FOR		SINGLE	reconstitution (supported by real time
INFUSION	INFUSION	3110/23T, 3111/23T	MEMBER S.A.	data)
	_	,		B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
				material/reagent/intermediate used in
DIAMICRO N	DIAMICRO N			the manufacturing process of the active
MODIFIED-	N MODIFIED-			substance For an excipient - European Pharmacopoeial Certificate of Suitability
RELEASE	RELEASE		LES	to the relevant Ph. Eur. Monograph -
TABLET	TABLET		LABORATOIR	Updated certificate from an already
30MG	30MG	10591/20T	ES SERVIER	approved manufacturer
_				B.III.1.a.2 B.III.1.a.2 - QUALITY
				CHANGES - CEP/TSE/MONOGRAPHS
				- Submission of a new or updated Ph.
				Eur. Certificate of suitability or deletion
				of Ph. Eur. certificate of suitability: For
				an active substance For a starting
DIAMORE	DIAMORE			material/reagent/intermediate used in
DIAMICRO	DIAMICRO			the manufacturing process of the active
N MODIFIED-	N MODIFIED-			substance For an excipient - European Pharmacopoeial Certificate of Suitability
RELEASE	RELEASE		LES	to the relevant Ph. Eur. Monograph -
TABLET	TABLET		LABORATOIR	Updated certificate from an already
60MG	60MG	10590/20T	ES SERVIER	approved manufacturer
00110				app. or our mundlatation

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 C.I.4 C.I.4 - SAFETY, EFFICACY,
ADACEL SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	ADACEL SUSPENSI ON FOR INJECTION IN PRE- FILLED SYRINGE	635/23T	SANOFI PASTEUR.	PHARMACOVIGILANCE CHANGES - HUMAN AND 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	B.III.1.a.2 B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer

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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 A.2.b A.2.b - ADMINISTRATIVE
MYCOZAL CAPSULE, HARD 150MG	MYCOZAL CAPSULE, HARD 150MG	3374/23T, 3375/23T	SAPIENS PHARMACEU TICALS LTD	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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 PHARMACEU TICALS 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 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
ALGOVIL TABLET, FILM COATED 200MG	ALGOVIL TABLET, FILM COATED 200MG	2574/23T	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
FUNGUSTA TIN CAPSULE, HARD 150MG	FUNGUSTA TIN 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- RESISTAN T, PROLONG ED RELEASE TABLETS 1200MG	MEZAVANT GASTRO- RESISTAN T, PROLONG ED RELEASE TABLETS 1200MG	2392/23T	TAKEDA PHARMACEU TICALS INTERNATION AL 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- RESISTAN T, PROLONG ED RELEASE TABLETS 1200MG	MEZAVANT GASTRO- RESISTAN T, PROLONG ED RELEASE TABLETS 1200MG	2392/23T	TAKEDA PHARMACEU TICALS INTERNATION AL 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
				C.I.2.a C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of a generic/hybrid/biosimilar
				medicinal products following
QUETRA	QUETRA			assessment of the same change for the reference product - Implementation of
ORAL	ORAL			change(s) for which no new additional
SOLUTION	SOLUTION		REMEDICA	data is required to be submitted by the
100MG/ML	100MG/ML	4523/23T	LTD	МАН
				C.I.5.z C.I.5.z - SAFETY, EFFICACY,
PEROFEN	PEROFEN			PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
TABLET.	TABLET,			MEDICINAL PRODUCTS - Change in
FILM	FILM			the legal status of a medicinal product
COATED	COATED		REMEDICA	for centrally authorised products - Other
200MG	200MG	4471/23T	LTD	variation
				C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
PEROFEN	PEROFEN			HUMAN AND VETERINARY
TABLET,	TABLET,			MEDICINAL PRODUCTS - Change in
FILM	FILM			the legal status of a medicinal product
COATED	COATED	4 474 /00T	REMEDICA	for centrally authorised products - Other
200MG	200MG	4471/23T	LTD	variation C.I.5.z C.I.5.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
PEROFEN	PEROFEN			MEDICINAL PRODUCTS - Change in
TABLET,	TABLET,			the legal status of a medicinal product
COATED 200MG	COATED 200MG	4470/23T	REMEDICA LTD	for centrally authorised products - Other variation
2001010	2001010	4470/231		C.I.5.z C.I.5.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
	PEROFEN			MEDICINAL PRODUCTS - Change in
TABLET, COATED	TABLET, COATED		REMEDICA	the legal status of a medicinal product for centrally authorised products - Other
200MG	200MG	4470/23T	LTD	variation
				C.I.5.z C.I.5.z - SAFETY, EFFICACY,
PEROFEN	PEROFEN			PHARMACOVIGILANCE CHANGES -
TABLET, FILM	TABLET, FILM			MEDICINAL PRODUCTS - Change in the legal status of a medicinal product
COATED	COATED		REMEDICA	for centrally authorised products - Other
400MG	400MG	4468/23T	LTD	variation
	DEDOET			C.I.5.z C.I.5.z - SAFETY, EFFICACY,
PEROFEN	PEROFEN			
400 TABLET,	400 TABLET,			HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change in
FILM	FILM			the legal status of a medicinal product
COATED	COATED		REMEDICA	for centrally authorised products - Other
400MG	400MG	4468/23T	LTD	variation
				C.I.5.z C.I.5.z - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
PEROFEN	PEROFEN			MEDICINAL PRODUCTS - Change in
TABLET,	TABLET,			the legal status of a medicinal product
COATED	COATED	4460/00T	REMEDICA	for centrally authorised products - Other
400MG	400MG	4469/23T	LTD	variation C.I.5.z C.I.5.z - SAFETY, EFFICACY,
PEROFEN	PEROFEN			PHARMACOVIGILANCE CHANGES -
TABLET,	TABLET,			HUMAN AND VETERINARY
COATED	COATED	4.400/007	REMEDICA	MEDICINAL PRODUCTS - Change in
400MG	400MG	4469/23T	LTD	the legal status of a medicinal product

				for centrally authorised products - Other
				variation
CANDIPLA S CREAM 2% W/W	CANDIPLA S 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
CANDIPLA S CREAM 2% W/W	CANDIPLA S 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
CANDIPLA S CREAM 2% W/W	CANDIPLA S 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
INTRATEC T SOLUTION FOR INFUSION 50G/L	INTRATEC T 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.
INTRATEC T SOLUTION FOR INFUSION 50G/L	INTRATEC T 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.

INTRATEC T SOLUTION FOR INFUSION 100G/L	INTRATEC T 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.
INTRATEC T SOLUTION FOR INFUSION 100G/L	INTRATEC T 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 HAEMOFIL TRATION	REGIOCIT SOLUTION FOR HAEMOFIL TRATION	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 PHARMACEU TICALS 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 PHARMACEU TICALS 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
FINGOLIM OD TECNIGEN CAPSULE, HARD 0.5MG	FINGOLIM OD 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

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				Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of 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 B.III.1.a.2 B.III.1.a.2 - QUALITY
DENAZOX TABLET 60MG	DENAZOX TABLET 60MG	4726/23T	REMEDICA LTD	CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer
REPRAT GAST	REPRAT GAST			B.II.b.2.a B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer,
TABLET, GASTRO- RESISTAN T 20MG	TABLET, GASTRO- RESISTAN T 20MG	4605/23T	DELORBIS PHARMACEU TICALS LTD	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 OROMUCO SAL SPRAY, SOLUTION (0.15 + 0.5)% w/v	BENCET MOUTH SPRAY OROMUCO SAL SPRAY, SOLUTION (0.15 + 0.5)% w/v	4884/23T, 4885/23T, 4886/23T	NASSINGTON	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 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 C.I.z C.I.z - SAFETY, EFFICACY,
ZYLORIC TABLET 100MG	ZYLORIC TABLET 100MG	4201/23T	ASPEN PHARMA TRADING LIMITED	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 -

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				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: For an active substance For a starting material/reagent/intermedia
DUINUM TABLET 50MG	DUINUM TABLET 50MG	5285/22T	MEDOCHEMIE	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 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
RETAFOR M TABLET, PROLONG ED- RELEASE 500MG	RETAFOR M TABLET, PROLONG ED- RELEASE 500MG	8827/22T	WIN MEDICA PHARMACEU TICAL 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)*
RETAFOR M TABLET, PROLONG ED- RELEASE 750MG	RETAFOR M TABLET, PROLONG ED- RELEASE 750MG	8826/22T	WIN MEDICA PHARMACEU TICAL 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)*
RETAFOR M TABLET, PROLONG ED- RELEASE 1000MG	RETAFOR M TABLET, PROLONG ED- RELEASE 1000MG	8825/22T	WIN MEDICA PHARMACEU TICAL 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)*
PAROXETI NE AUROBIND O TABLET, FILM COATED 20MG	PAROXETI NE AUROBIND O 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
PAROXETI NE AUROBIND O TABLET, FILM COATED 30MG	PAROXETI NE AUROBIND O 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
MANTOME D TABLET, FILM COATED 20MG	MANTOME D TABLET, FILM COATED 20MG	3179/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOME D TABLET, FILM COATED 10MG	MANTOME D TABLET, FILM COATED 10MG	3180/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOME D TABLET, FILM COATED 5MG	MANTOME D TABLET, FILM COATED 5MG	3178/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOME D TABLET, FILM COATED 15MG	MANTOME D TABLET, FILM COATED 15MG	3177/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOME D TABLET, FILM COATED 20MG	MANTOME D TABLET, FILM COATED 20MG	3186/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation
MANTOME D TABLET, FILM	MANTOME D TABLET, FILM	3187/23T	MEDOCHEMIE LTD	B.I.z B.I.z - Quality change - Active substance - Other variation

COATED	COATED			
10MG	10MG			
D TABLET, FILM	D TABLET, FILM			
COATED	COATED		MEDOCHEMIE	B.I.z B.I.z - Quality change - Active
15MG	15MG	3184/23T	LTD	substance - Other variation
MANTOME D TABLET,	MANTOME D TABLET,			
FILM	FILM			
COATED	COATED		MEDOCHEMIE	B.I.z B.I.z - Quality change - Active
5MG	5MG	3185/23T	LTD	substance - Other variation
SUGAMMA DEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	SUGAMMA DEX SAPIENS SOLUTION FOR INJECTION 100MG/ML	4671/23T, 4672/23T, 4673/23T	SAPIENS PHARMACEU TICALS 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	MUNDIPHARM A PHARMACEU TICALS 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

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OXYNORM CAPSULE, HARD 5MG	OXYNORM CAPSULE, HARD 5MG	2318/22T	MUNDIPHARM A PHARMACEU TICALS 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	MUNDIPHARM A PHARMACEU TICALS 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
OXYCONTI N TABLET, PROLONG ED- RELEASE 80MG	OXYCONTI N TABLET, PROLONG ED- RELEASE 80MG	2315/22T	MUNDIPHARM A PHARMACEU TICALS 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	MUNDIPHARM A PHARMACEU TICALS 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
OXYCONTI N TABLET, PROLONG ED- RELEASE 10MG	OXYCONTI N TABLET, PROLONG ED- RELEASE 10MG	2317/22T	MUNDIPHARM A PHARMACEU TICALS 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
OXYCONTI N TABLET, PROLONG ED-	OXYCONTI N TABLET, PROLONG ED-	2316/22T	MUNDIPHARM A PHARMACEU TICALS 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

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RELEASE	RELEASE			Characteristics, Labelling or Package
40MG	40MG			Leaflet of human medicinal products
				intended to implement the outcome of a
				procedure 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.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
OXYCONTI	OXYCONTI			intended to implement the outcome of a
N TABLET,	N TABLET,			procedure concerning PSUR or PASS,
PROLONG	PROLONG		MUNDIPHARM	or the outcome of the assessment done
ED-	ED-			by the competent authority under
RELEASE 5MG	RELEASE 5MG	2311/22T	PHARMACEU TICALS LTD	Articles 45 or 46 of Regulation
SiviG	SIVIG	2311/221	TICALS LTD	1901/2006 - Other variation C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES -
				HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
				intended to implement the outcome of a
OXYNORM	OXYNORM			procedure concerning PSUR or PASS,
LIQUID	LIQUID		MUNDIPHARM	or the outcome of the assessment done
ORAL	ORAL		Α	by the competent authority under
SOLUTION	SOLUTION		PHARMACEU	Articles 45 or 46 of Regulation
5MG/5ML	5MG/5ML	2312/22T	TICALS LTD	1901/2006 - Other variation
				C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
				Leaflet of human medicinal products
OXYCONTI	OXYCONTI			intended to implement the outcome of a
N TABLET,	N TABLET,			procedure concerning PSUR or PASS,
PROLONG	PROLONG		MUNDIPHARM	or the outcome of the assessment done
ED-	ED-		A	by the competent authority under
RELEASE	RELEASE		PHARMACEU	Articles 45 or 46 of Regulation
20MG	20MG	2314/22T	TICALS LTD	1901/2006 - Other variation
				C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
				in the Summary of Product
				Characteristics, Labelling or Package
OXYNORM	OXYNORM			Leaflet of human medicinal products
SOLUTION	SOLUTION			intended to implement the outcome of a
FOR	FOR			procedure concerning PSUR or PASS,
INJECTION	INJECTION		MUNDIPHARM	or the outcome of the assessment done
OR	OR		A	by the competent authority under
INFUSION	INFUSION	0000/00T	PHARMACEU	Articles 45 or 46 of Regulation
50MG/ML	50MG/ML	2322/22T	TICALS LTD	1901/2006 - Other variation
				C.I.3.z C.I.3.z - SAFETY, EFFICACY,
				PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY
				MEDICINAL PRODUCTS - Change(s)
OXYNORM	OXYNORM			in the Summary of Product
CONCENT	CONCENT			Characteristics, Labelling or Package
			MUNDIPHARM	Leaflet of human medicinal products
RATE	RATE			
RATE ORAL	ORAL		А	intended to implement the outcome of a
		2313/22T	A PHARMACEU TICALS LTD	

r	r	Γ		Г
				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	PHARMATHE N 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	PHARMATHE N 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	PHARMATHE N 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".
ATORVAST ATIN SANDOZ TABLET, FILM COATED 10MG	ATORVAST ATIN 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.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
ATORVAST ATIN SANDOZ TABLET, FILM	ATORVAST ATIN SANDOZ TABLET, FILM			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
COATED 20MG	COATED 20MG	11195 - 11218/20T	SANDOZ GMBH	

	1			
				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
ATORVAST ATIN SANDOZ TABLET, FILM COATED 40MG	ATORVAST ATIN SANDOZ TABLET, FILM COATED 40MG	11171 -11194/20T	SANDOZ GMBH	
401010	401010	11171-11194/201	GLAXOSMITH	
PANADOL COLD AND FLU TABLET, FILM COATED	PANADOL COLD AND FLU TABLET, FILM COATED	6134/15T	ΚLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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	PHARMATHE N 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	LEFLON			B.III.1.a). 2 Updated certificate from an already approved manufacturer
TABLET, FILM COATED 20MG	TABLET, FILM COATED 20MG	8811/19T	PHARMATHE N S.A.	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	PHARMATHE N 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
ATORVAST ATIN SANDOZ TABLET, FILM COATED 40MG	ATORVAST ATIN 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
ATORVAST ATIN SANDOZ TABLET, FILM COATED 30MG	ATORVAST ATIN 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
ATORVAST ATIN SANDOZ TABLET, FILM COATED 20MG	ATORVAST ATIN 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
ATORVAST ATIN SANDOZ TABLET, FILM COATED 10MG	ATORVAST ATIN 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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	GLAXOSMITH KLINE ΚΑΤΑΝΑΛΩΤΙ ΚΑ 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
ATORVAST ATIN SANDOZ TABLET,	ATORVAST ATIN SANDOZ TABLET,	4029/19T	SANDOZ GMBH	C.I.3. z) Other variation -alignment to PSUFU/00010347/201710/B;

FILM COATED	FILM COATED			
40MG	40MG			
ATORVAST	ATORVAST			
ATIN	ATIN			
SANDOZ	SANDOZ			
TABLET,	TABLET,			
FILM COATED	FILM COATED		SANDOZ	C 2, 7) Other variation alignment to
30MG	30MG	4028/19T	GMBH	C.I.3. z) Other variation -alignment to PSUFU/00010347/201710/B;
ATORVAST	ATORVAST	4020/131	OMDIT	1 001 0/00010347/201110/B,
ATIN	ATIN			
SANDOZ	SANDOZ			
TABLET,	TABLET,			
FILM	FILM		0.000	
COATED	COATED	4007/40T	SANDOZ	C.I.3. z) Other variation -alignment to
20MG ATORVAST	20MG ATORVAST	4027/19T	GMBH	PSUFU/00010347/201710/B;
ATIN	ATIN			
SANDOZ	SANDOZ			
TABLET,	TABLET,			
FILM	FILM			
COATED	COATED		SANDOZ	C.I.3. z) Other variation -alignment to
10MG	10MG	4026/19T	GMBH	PSUFU/00010347/201710/B;
DIAMICRO	DIAMICRO			
				R II d 2 d Change in test procedure ter
MODIFIED- RELEASE	MODIFIED- RELEASE		LES	B.II.d.2.d- Change in test procedure tor the finished product-Other changes to a
TABLET	TABLET		LABORATOIR	test procedure (including replacemet of
60MG	60MG	3965/19T	ES SERVIER	addition)
ATORVAST	ATORVAST			
ATIN	ATIN			
SANDOZ	SANDOZ			
TABLET,	TABLET,			
FILM COATED	FILM COATED		SANDOZ	C.I.3. z) Other variation -Align PI with PSUFU/00010347/201710/A and
40MG	40MG	3397/19T	GMBH	adaption to Excipients GL
ATORVAST	ATORVAST	0007/101	GMBH	
ATIN	ATIN			
SANDOZ	SANDOZ			
TABLET,	TABLET,			
FILM	FILM		041007	C.I.3. z) Other variation -Align PI with
COATED	COATED	2206/10T		PSUFU/00010347/201710/A and
30MG ATORVAST	30MG ATORVAST	3396/19T	GMBH	adaption to Excipients GL
ATIN	ATIN			
SANDOZ	SANDOZ			
TABLET,	TABLET,			
FILM	FILM			C.I.3. z) Other variation -Align PI with
COATED	COATED		SANDOZ	PSUFU/00010347/201710/A and
20MG	20MG	3395/19T	GMBH	adaption to Excipients GL
ATIN SANDOZ	ATIN SANDOZ			
TABLET,	TABLET,			
FILM	FILM			C.I.3. z) Other variation -Align PI with
COATED	COATED		SANDOZ	PSUFU/00010347/201710/A and
10MG	10MG	3394/19T	GMBH	adaption to Excipients GL
ATORVAST	ATORVAST			
ATIN	ATIN			
SANDOZ	SANDOZ			
TABLET, FILM	TABLET, FILM			C.I.3. z) Other variation -Align PI with
COATED	COATED		SANDOZ	PSUFU/00010347/201710/A and
40MG	40MG	2419/19T	GMBH	adaption to Excipients GL
ATORVAST	ATORVAST			
	ATIN			
ATIN				
SANDOZ	SANDOZ			C.I.3. z) Other variation -Align PI with
	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	COATED			
30MG ATORVAST	30MG ATORVAST			
ATIN	ATIN			
SANDOZ	SANDOZ			
TABLET,	TABLET,			C 1.2 =) Other vertetion Allow Directly
FILM COATED	FILM COATED		SANDOZ	C.I.3. z) Other variation -Align PI with PSUFU/00010347/201710/A and
20MG	20MG	2417/19T	GMBH	adaption to Excipients GL
ATORVAST	ATORVAST			
ATIN SANDOZ	ATIN SANDOZ			
TABLET.	TABLET,			
FILM	FILM			C.I.3. z) Other variation -Align PI with
COATED	COATED	2440/40T	SANDOZ	PSUFU/00010347/201710/A and
10MG	10MG	2416/19T	GMBH	adaption to Excipients GL B.I.a.1Change in manufacturer of a
				starting material/reagent/intermediate
				used in the manufacturing process of
ERLOTINIB	ERLOTINIB			the active substance or change in the manufacturer (including where relevant
SANDOZ TABLET,	SANDOZ TABLET,			quality control testing sites) of the active
FILM	FILM			substance, where no Ph. Eur. Certificate
COATED	COATED	0774/40T	SANDOZ	of Suitability is part of the approved
150MG	150MG	8771/18T	GMBH	dossier B.I.a.1 c)The proposed manufacturer
				uses a substantially different route of
				synthesis or manufacturing conditions,
EVECET	EVECET			which may have a potential change important quality characteristics of the
TABLET.	TABLET,			active substance, such as qualitative
PROLONG	PROLONG			and/or quantitative impurity profile
ED-	ED-		PT	requiring qualification, or
RELEASE 8MG	RELEASE 8MG	8209/18T	HADJIGEORGI OU CO LTD	physicochemical properties impacting on biovailability
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG ED-	PROLONG ED-		РТ	C.I.2. a) Implementation of change(s)
RELEASE	RELEASE		HADJIGEORGI	for which no new additional data is
4MG	4MG	8208/18T	OU CO LTD	required to be submitted by the MAH
EVECET TABLET,	EVECET TABLET,			
PROLONG	PROLONG			
ED-	ED-		PT	C.I.2. a) Implementation of change(s)
RELEASE 3MG	RELEASE 3MG	8207/18T	HADJIGEORGI OU CO LTD	for which no new additional data is required to be submitted by the MAH
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG ED-	PROLONG ED-		РТ	C.I.2. a) Implementation of change(s)
RELEASE	RELEASE		HADJIGEORGI	for which no new additional data is
2MG	2MG	8206/18T	OU CO LTD	required to be submitted by the MAH
ATORVAST	ATORVAST ATIN			
ATIN SANDOZ	SANDOZ			
TABLET,	TABLET,			
FILM	FILM			C.I.3. a) Implementation of wording
COATED 40MG	COATED 40MG	7454/18T	SANDOZ GMBH	agreed by the competent authority- alignment to PSUSA/00010347/201710
ATORVAST	ATORVAST			
ATIN	ATIN			
SANDOZ TABLET,	SANDOZ TABLET,			
FILM	FILM			C.I.3. a) Implementation of wording
COATED	COATED	.	SANDOZ	agreed by the competent authority-
30MG	30MG	7453/18T	GMBH	alignment to PSUSA/00010347/201710
ATORVAST ATIN	ATORVAST ATIN		SANDOZ	C.I.3. a) Implementation of wording agreed by the competent authority-
SANDOZ	SANDOZ	7452/18T	GMBH	alignment to PSUSA/00010347/201710

		I	Τ	
TABLET, FILM	TABLET, FILM			
COATED				
20MG	20MG			
ATORVAST	ATORVAST			
ATIN	ATIN			
SANDOZ	SANDOZ			
TABLET,	TABLET,			
FILM	FILM			C.I.3. a) Implementation of wording
COATED	COATED		SANDOZ	agreed by the competent authority-
10MG	10MG	7451/18T	GMBH	alignment to PSUSA/00010347/201710
				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
LEFLON	LEFLON			current QRD template (incl.
TABLET,	TABLET,			implementation of the safety features on
FILM	FILM			the packaging, section 17 and 18 [Doc.
COATED	COATED		PHARMATHE	Ref: CMDh/345/2016; February 2016])
100MG	100MG	5662/18T	N S.A.	and adaptation to excipient guidelines
				C.I.2. a) Implementation of change(s)
				for which no new additional data is
				required to be submitted by the MAH
				Adoptation of the CDC and DU, to the
				Adaptation of the SPC and PIL to the reference product Arava (EU/1/99/118),
				furthermore implementation of the
LEFLON	LEFLON			current QRD template (incl.
TABLET,	TABLET,			implementation of the safety features on
FILM	FILM			the packaging, section 17 and 18 [Doc.
COATED	COATED		PHARMATHE	Ref: CMDh/345/2016; February 2016])
20MG	20MG	5661/18T	N S.A.	and adaptation to excipient guidelines
				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
				· · · · · ·
LEFLON TABLET,	LEFLON TABLET,			current QRD template (incl. implementation of the safety features on
FILM	FILM			the packaging, section 17 and 18 [Doc.
COATED	COATED		PHARMATHE	Ref: CMDh/345/2016; February 2016])
10MG	10MG	5660/18T	N S.A.	and adaptation to excipient guidelines
			1	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
	D 4 1 1 D 4			severe skin reactions such as acute
PANADOL	PANADOL		GLAXOSMITH	generalized exanthematous pustulosis
COLD AND	COLD AND		KLINE	and this adverse drug reaction has been
				listed with the frequency not known.
TABLET, FILM	TABLET, FILM		HEALTHCARE (UK) TRADING	Consequentially, the PIL and Sections 4.4 and 4.8 of the SPC have been
COATED		4942/18T	LIMITED	updated.
				C.I. z) Other variation C.I.2. a)
ATORVAST	ATORVAST			Implementation of change(s) for which
ATIN	ATIN			no new additional data is required to be
SANDOZ	SANDOZ			submitted by the MAH alignment to
TABLET,	TABLET,			originator-product Sortis (lastly
FILM	FILM			approved DE/H/XXXX/WS/031) +
COATED	COATED		SANDOZ	CMDh_Wording_on_statins_10_2015 +
40MG	40MG	638-639/18T	GMBH	ATD/UID;
ATORVAST	ATORVAST			C.I. z) Other variation C.I.2. a)
ATIN SANDOZ			SANDOZ	Implementation of change(s) for which
	SANDOZ		SANDOZ	no new additional data is required to be
TABLET,	TABLET,	636-637/18T	GMBH	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;
ATORVAST ATIN SANDOZ TABLET, FILM COATED 20MG	ATORVAST ATIN 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;
ATORVAST ATIN SANDOZ TABLET, FILM COATED 10MG	ATORVAST ATIN 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	PHARMATHE N 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	PHARMATHE N 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	PHARMATHE N 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	PHARMATHE N 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	PHARMATHE N 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	PHARMATHE N 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 (

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				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	EVECET			
TABLET,	TABLET,			
PROLONG	PROLONG			A.1. Change in the name and/or
ED-	ED-		РТ	address of the MAH
RELEASE	RELEASE		HADJIGEORGI	A.2. b) for Nationally Authorised
8MG	8MG	8150, 8153/16T	OU CO LTD	Products
EVECET	EVECET	8130, 8133/101	OU CO LID	Tioducis
TABLET,	TABLET,			
PROLONG	PROLONG			A.1. Change in the name and/or
ED-	ED-		ΡT	address of the MAH
RELEASE	RELEASE		HADJIGEORGI	A.2. b) for Nationally Authorised
4MG	4MG	8149, 8152/16T	OU CO LTD	Products
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG	PROLONG			A.1. Change in the name and/or
			РТ	address of the MAH
ED-	ED-			
RELEASE	RELEASE		HADJIGEORGI	A.2. b) for Nationally Authorised
2MG	2MG	8148, 8151/16T	OU CO LTD	Products
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG	PROLONG			
ED-	ED-		РТ	
RELEASE	RELEASE	0044/407	HADJIGEORGI	
8MG	8MG	2644/16T	OU CO LTD	C.I.3. z) Other variation
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG	PROLONG			
ED-	ED-		РТ	
RELEASE	RELEASE		HADJIGEORGI	
-	-	2642/46T		C 2 =) Other variation
4MG	4MG	2643/16T	OU CO LTD	C.I.3. z) Other variation
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG	PROLONG			
ED-	ED-		РТ	
RELEASE	RELEASE		HADJIGEORGI	
3MG	3MG	2642/16T	OU CO LTD	C.I.3. z) Other variation
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG	PROLONG			
ED-	ED-		ΡT	
RELEASE	RELEASE		HADJIGEORGI	
2MG	2MG	2641/16T	OU CO LTD	C.I.3. z) Other variation
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG	PROLONG			
ED-	ED-		РТ	
				A 2 b) for Notionally Authorized
RELEASE	RELEASE	2520/4 CT	HADJIGEORGI	A.2. b) for Nationally Authorised
8MG	8MG	2539/16T	OU CO LTD	Products
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG	PROLONG			
ED-	ED-		РТ	
RELEASE	RELEASE		HADJIGEORGI	A.2. b) for Nationally Authorised
4MG	4MG	2538/16T	OU CO LTD	Products
EVECET	EVECET			
TABLET,	TABLET,			
PROLONG	PROLONG			
ED-	ED-		ΡT	
RELEASE	RELEASE		HADJIGEORGI	A.2. b) for Nationally Authorised
3MG	3MG	2537/16T	OU CO LTD	Products
EVECET	EVECET			
TABLET,	TABLET,		РТ	
				A. D. h) for Notionally Authority -
PROLONG	PROLONG	0500/407	HADJIGEORGI	A.2. b) for Nationally Authorised
	ED-	2536/16T	OU CO LTD	Products
ED-				

RELEASE 2MG	RELEASE 2MG			
EVECET TABLET, PROLONG	EVECET TABLET, PROLONG			
ED-	ED-		РТ	
RELEASE 8MG	RELEASE 8MG	1946/16T	HADJIGEORGI OU CO LTD	Transfer of marketing Authorisation holder
EVECET TABLET, PROLONG	EVECET TABLET, PROLONG			
ED- RELEASE	ED- RELEASE		P T HADJIGEORGI	Transfer of marketing Authorisation
4MG	4MG	1945/16T	OU CO LTD	holder
EVECET TABLET, PROLONG ED-	EVECET TABLET, PROLONG ED-		PT	
RELEASE 3MG	RELEASE 3MG	1944/16T	HADJIGEORGI OU CO LTD	Transfer of marketing Authorisation holder
EVECET TABLET, PROLONG	EVECET TABLET, PROLONG			
ED-	ED-			Transfer of monitorian Authorization
RELEASE 2MG	RELEASE 2MG	1943/16T	HADJIGEORGI OU CO LTD	Transfer of marketing Authorisation holder