Authorisation Number	Licensed Product Name	Case Submission Status	Case Reference Number (HL)	Case Reference Number	Effective Date of Granting	Submission Type	Submission Category	Work type	Type of Procedure	Case Reason
PL 00031/0160	ROACCUTANE 20 MG SOFT CAPSULES	GRANTED	PL 00031/0160-0180	PL 00031/0160-0180	02/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER THE RISK MANAGEMENT PLAN OF THE FINISHED PRODUCT, FURTHER TO THE APPROVAL OF THE TWO POST-AUTHORIZATION SAFETY STUDIES (PASS) WHICH WERE IMPOSED AS PART OF THE ARTICLE 31 PHARMACOVIGILANCE REFERRAL PROCEDURE FOR RETINOID-CONTAINING MEDICINAL PRODUCTS (PROCEDURE NUMBER: EMEA/H/A-31/1446).
PL 00031/0617	ROACCUTANE 10MG SOFT CAPSULES	GRANTED	PL 00031/0617-0126	PL 00031/0617-0126	02/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER THE RISK MANAGEMENT PLAN OF THE FINISHED PRODUCT, FURTHER TO THE APPROVAL OF THE TWO POST-AUTHORIZATION SAFETY STUDIES (PASS) WHICH WERE IMPOSED AS PART OF THE ARTICLE 31 PHARMACOVIGILANCE REFERRAL PROCEDURE FOR RETINOID-CONTAINING MEDICINAL PRODUCTS (PROCEDURE

										NUMBER: EMEA/H/A-31/1446).
PL 10085/0052	JEXT 150 MICROGRAMS SOLUTION FOR INJECTION IN PRE-FILLED PEN	GRANTED	PL 10085/0052-0059	PL 10085/0052-0059	02/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4, 4.6 AND 4.8 BASED ON THE NEW ESTABLISHED COMPANY CORE SAFETY INFORMATION (CCSI) FOR JEXT. 2) TO UPDATE SECTIONS 6.4 AND 6.5 AND PL SECTION 5 IN ORDER TO INCLUDE INFORMATION ON THE PURPOSE AND USE OF THE CARRY CASE
PL 10085/0052	JEXT 150 MICROGRAMS SOLUTION FOR INJECTION IN PRE-FILLED PEN	GRANTED	PL 10085/0052-0059	PL 10085/0052-0059	02/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4, 4.6 AND 4.8 BASED ON THE NEW ESTABLISHED COMPANY CORE SAFETY INFORMATION (CCSI) FOR JEXT. 2) TO UPDATE SECTIONS 6.4 AND 6.5 AND PL SECTION 5 IN ORDER TO INCLUDE INFORMATION ON THE PURPOSE AND USE OF THE CARRY CASE
PL 10085/0053	JEXT 300 MICROGRAMS SOLUTION FOR INJECTION IN PRE-FILLED PEN	GRANTED	PL 10085/0053-0059	PL 10085/0053-0059	02/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4, 4.6 AND 4.8 BASED ON THE NEW ESTABLISHED COMPANY CORE SAFETY INFORMATION (CCSI) FOR JEXT.

										2) TO UPDATE SECTIONS 6.4 AND 6.5 AND PL SECTION 5 IN ORDER TO INCLUDE INFORMATION ON THE PURPOSE AND USE OF THE CARRY CASE
PL 10085/0053	JEXT 300 MICROGRAMS SOLUTION FOR INJECTION IN PRE-FILLED PEN	GRANTED	PL 10085/0053-0059	PL 10085/0053-0059	02/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4, 4.6 AND 4.8 BASED ON THE NEW ESTABLISHED COMPANY CORE SAFETY INFORMATION (CCSI) FOR JEXT. 2) TO UPDATE SECTIONS 6.4 AND 6.5 AND PL SECTION 5 IN ORDER TO INCLUDE INFORMATION ON THE PURPOSE AND USE OF THE CARRY CASE
PL 14776/0098	PROVIGIL 100MG TABLETS	GRANTED	PL 14776/0098-0054	PL 14776/0098-0054	04/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN TO INCLUDE THE PROTOCOL FOR A RETROSPECTIVE PASS TO FURTHER INVESTIGATE THE RISK OF CONGENITAL MALFORMATIONS ACCORDING TO COMMITMENT ESTABLISHED WITH THE OUTCOME OF DE/H/3259/II/026/G VARIATION.

PL 00057/1296	ZOTON FASTAB 15MG	GRANTED	PL 00057/1296-0029	PL 00057/1296-0029	09/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO INCLUDE WARNINGS FROM POST-MARKETING PHARMACOVIGILANCE DATA REGARDING HYPOMAGNESAEMIA. CONSEQUENTIALLY, THE PIL TEXT HAS BEEN UPDATED.
PL 00057/1297	ZOTON FASTAB 30MG	GRANTED	PL 00057/1297-0029	PL 00057/1297-0029	09/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO INCLUDE WARNINGS FROM POST-MARKETING PHARMACOVIGILANCE DATA REGARDING HYPOMAGNESAEMIA. CONSEQUENTIALLY, THE PIL TEXT HAS BEEN UPDATED.
PL 04425/0318	SURGAM TABLETS 300MG	GRANTED	PL 04425/0318-0060	PL 04425/0318-0060	09/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.8 THE SMPC FOLLOWING A WORK-SHARING PROCEDURE ACCORDING TO ARTICLE 20 OF COMMISSION REGULATION (EC) NO 1234/2008, TO ADD INFORMATION REGARDING EXACERBATION OF INFECTIONS IN THE PRODUCT INFORMATION . CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

										ADDITIONAL INFORMATION HAS BEEN ADDED TO SECTION 9 OF THE SMPC.
PL 18945/0002	SALCROZINE 500MG GASTRO-RESISTANT TABLETS	GRANTED	PL 18945/0002-0008	PL 18945/0002-0008	10/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.6, 4.8, 5.3, 6.1 AND 6.5 OF THE SMPC TO ALIGN WITH APPROVED PROCEDURES PT/H/2280-2281/001-002 (MESALAZINE SUPPOSITORIES) AND ES/H/0587/0588/002 (MESALAZINE 1000 MG GASTRO-RESISTANT TABLETS) AND PRODUCT INFORMATION RECOMMENDATIONS RAISED DURING RUP ES/H/0588/001/E/001. CONSEQUENTLY, THE PACKAGE LABELLING AND PIL HAVE BEEN UPDATED.
PL 10592/0085	REQUIP 0.25MG	GRANTED	PL 10592/0085-0120	PL 10592/0085-0120	14/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN COMPRISING FOLLOWING CHANGES: - COMBINATION OF THE TWO EXISTING ROPINIROLE EURMPS FORMAT (PD-PR V2, AND RLS-IR V2) INTO ONE COMMON, CONSOLIDATED UPDATED EU-RMP TEMPLATE, WHICH WAS BASED ON PUBLICATION OF GVP MODULE V REV.2 ON 30 MARCH 2017 AND

										WILL INCLUDE BOTH FORMULATIONS & INDICATIONS. - PROPOSING THE REMOVAL OF ALL IMPORTANT IDENTIFIED/POTENTIAL RISKS AND MISSING INFORMATION FROM BOTH PRIOR EURMPS IN LIGHT OF THE CHANGES TO THE SAFETY CONCERNS DEFINITIONS IN THE GVP V R2, AS WELL AS THE EXTENSIVE POST-MARKETING EXPERIENCE. - PROVISION OF RESULTS OF LONG-TERM SAFETY DATA FOR PARKINSON'S DISEASE (PD) WHICH WERE ONGOING AT THE TIME OF THE PD-PR EURMP SUBMISSION.
PL 10592/0087	REQUIP 1MG	GRANTED	PL 10592/0087-0129	PL 10592/0087-0129	14/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN COMPRISING FOLLOWING CHANGES: - COMBINATION OF THE TWO EXISTING ROPINIROLE EURMPS FORMAT (PD-PR V2, AND RLS-IR V2) INTO ONE COMMON, CONSOLIDATED UPDATED EU-RMP TEMPLATE, WHICH WAS BASED ON PUBLICATION

										OF GVP MODULE V REV.2 ON 30 MARCH 2017 AND WILL INCLUDE BOTH FORMULATIONS & INDICATIONS. - PROPOSING THE REMOVAL OF ALL IMPORTANT IDENTIFIED/POTENTIAL RISKS AND MISSING INFORMATION FROM BOTH PRIOR EURMPS IN LIGHT OF THE CHANGES TO THE SAFETY CONCERNS DEFINITIONS IN THE GVP V R2, AS WELL AS THE EXTENSIVE POST-MARKETING EXPERIENCE. - PROVISION OF RESULTS OF LONG-TERM SAFETY DATA FOR PARKINSON'S DISEASE (PD) WHICH WERE ONGOING AT THE TIME OF THE PD-PR EURMP SUBMISSION.
PL 10592/0088	REQUIP 2MG	GRANTED	PL 10592/0088-0119	PL 10592/0088-0119	14/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN COMPRISING FOLLOWING CHANGES: - COMBINATION OF THE TWO EXISTING ROPINIROLE EURMPS FORMAT (PD-PR V2, AND RLS-IR V2) INTO ONE COMMON, CONSOLIDATED UPDATED EU-RMP

										TEMPLATE, WHICH WAS BASED ON PUBLICATION OF GVP MODULE V REV.2 ON 30 MARCH 2017 AND WILL INCLUDE BOTH FORMULATIONS & INDICATIONS. - PROPOSING THE REMOVAL OF ALL IMPORTANT IDENTIFIED/POTENTIAL RISKS AND MISSING INFORMATION FROM BOTH PRIOR EURMPS IN LIGHT OF THE CHANGES TO THE SAFETY CONCERNS DEFINITIONS IN THE GVP V R2, AS WELL AS THE EXTENSIVE POST-MARKETING EXPERIENCE. - PROVISION OF RESULTS OF LONG-TERM SAFETY DATA FOR PARKINSON'S DISEASE (PD) WHICH WERE ONGOING AT THE TIME OF THE PD-PR EURMP SUBMISSION.
PL 10592/0089	REQUIP 5MG	GRANTED	PL 10592/0089-0115	PL 10592/0089-0115	14/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN COMPRISING FOLLOWING CHANGES: - COMBINATION OF THE TWO EXISTING ROPINIROLE EURMPS FORMAT (PD-PR V2, AND RLS-IR V2) INTO ONE

										COMMON, CONSOLIDATED UPDATED EU-RMP TEMPLATE, WHICH WAS BASED ON PUBLICATION OF GVP MODULE V REV.2 ON 30 MARCH 2017 AND WILL INCLUDE BOTH FORMULATIONS & INDICATIONS. - PROPOSING THE REMOVAL OF ALL IMPORTANT IDENTIFIED/POTENTIAL RISKS AND MISSING INFORMATION FROM BOTH PRIOR EURMPS IN LIGHT OF THE CHANGES TO THE SAFETY CONCERNS DEFINITIONS IN THE GVP V R2, AS WELL AS THE EXTENSIVE POST-MARKETING EXPERIENCE. - PROVISION OF RESULTS OF LONG-TERM SAFETY DATA FOR PARKINSON'S DISEASE (PD) WHICH WERE ONGOING AT THE TIME OF THE PD-PR EURMP SUBMISSION.
PL 10592/0293	REQUIP XL 2 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0293-0069	PL 10592/0293-0069	14/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN COMPRISING FOLLOWING CHANGES: - COMBINATION OF THE TWO EXISTING ROPINIROLE EURMPS

										FORMAT (PD-PR V2, AND RLS-IR V2) INTO ONE COMMON, CONSOLIDATED UPDATED EU-RMP TEMPLATE, WHICH WAS BASED ON PUBLICATION OF GVP MODULE V REV.2 ON 30 MARCH 2017 AND WILL INCLUDE BOTH FORMULATIONS & INDICATIONS. - PROPOSING THE REMOVAL OF ALL IMPORTANT IDENTIFIED/POTENTIAL RISKS AND MISSING INFORMATION FROM BOTH PRIOR EURMPS IN LIGHT OF THE CHANGES TO THE SAFETY CONCERNS DEFINITIONS IN THE GVP V R2, AS WELL AS THE EXTENSIVE POST-MARKETING EXPERIENCE. - PROVISION OF RESULTS OF LONG-TERM SAFETY DATA FOR PARKINSON'S DISEASE (PD) WHICH WERE ONGOING AT THE TIME OF THE PD-PR EURMP SUBMISSION.
PL 10592/0295	REQUIP XL 4 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0295-0065	PL 10592/0295-0065	14/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN COMPRISING FOLLOWING CHANGES: - COMBINATION OF THE

								WORKSHARING		TWO EXISTING ROPINIROLE EURMPS FORMAT (PD-PR V2, AND RLS-IR V2) INTO ONE COMMON, CONSOLIDATED UPDATED EU-RMP TEMPLATE, WHICH WAS BASED ON PUBLICATION OF GVP MODULE V REV.2 ON 30 MARCH 2017 AND WILL INCLUDE BOTH FORMULATIONS & INDICATIONS. - PROPOSING THE REMOVAL OF ALL IMPORTANT IDENTIFIED/POTENTIAL RISKS AND MISSING INFORMATION FROM BOTH PRIOR EURMPS IN LIGHT OF THE CHANGES TO THE SAFETY CONCERNS DEFINITIONS IN THE GVP V R2, AS WELL AS THE EXTENSIVE POST-MARKETING EXPERIENCE. - PROVISION OF RESULTS OF LONG-TERM SAFETY DATA FOR PARKINSON'S DISEASE (PD) WHICH WERE ONGOING AT THE TIME OF THE PD-PR EURMP SUBMISSION.
PL 10592/0296	REQUIP XL 8 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0296-0063	PL 10592/0296-0063	14/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN COMPRISING FOLLOWING CHANGES:

								RD) - CMS WORKSHARING		- COMBINATION OF THE TWO EXISTING ROPINIROLE EURMPS FORMAT (PD-PR V2, AND RLS-IR V2) INTO ONE COMMON, CONSOLIDATED UPDATED EU-RMP TEMPLATE, WHICH WAS BASED ON PUBLICATION OF GVP MODULE V REV.2 ON 30 MARCH 2017 AND WILL INCLUDE BOTH FORMULATIONS & INDICATIONS. - PROPOSING THE REMOVAL OF ALL IMPORTANT IDENTIFIED/POTENTIAL RISKS AND MISSING INFORMATION FROM BOTH PRIOR EURMPS IN LIGHT OF THE CHANGES TO THE SAFETY CONCERNS DEFINITIONS IN THE GVP V R2, AS WELL AS THE EXTENSIVE POST-MARKETING EXPERIENCE. - PROVISION OF RESULTS OF LONG-TERM SAFETY DATA FOR PARKINSON'S DISEASE (PD) WHICH WERE ONGOING AT THE TIME OF THE PD-PR EURMP SUBMISSION.

PL 19494/0033	ADARTREL 0.25 MG FILM-COATED TABLETS	GRANTED	PL 19494/0033-0078	PL 19494/0033-0078	14/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN COMPRISING FOLLOWING CHANGES: - COMBINATION OF THE TWO EXISTING ROPINIROLE EURMPS FORMAT (PD-PR V2, AND RLS-IR V2) INTO ONE COMMON, CONSOLIDATED UPDATED EU-RMP TEMPLATE, WHICH WAS BASED ON PUBLICATION OF GVP MODULE V REV.2 ON 30 MARCH 2017 AND WILL INCLUDE BOTH FORMULATIONS & INDICATIONS. - PROPOSING THE REMOVAL OF ALL IMPORTANT IDENTIFIED/POTENTIAL RISKS AND MISSING INFORMATION FROM BOTH PRIOR EURMPS IN LIGHT OF THE CHANGES TO THE SAFETY CONCERNS DEFINITIONS IN THE GVP V R2, AS WELL AS THE EXTENSIVE POST-MARKETING EXPERIENCE. - PROVISION OF RESULTS OF LONG-TERM SAFETY DATA FOR PARKINSON'S DISEASE (PD) WHICH WERE ONGOING AT THE

										TIME OF THE PD-PR EURMP SUBMISSION.
PL 19494/0034	ADARTREL 0.5 MG FILM-COATED TABLETS	GRANTED	PL 19494/0034-0078	PL 19494/0034-0078	14/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN COMPRISING FOLLOWING CHANGES: - COMBINATION OF THE TWO EXISTING ROPINIROLE EURMPS FORMAT (PD-PR V2, AND RLS-IR V2) INTO ONE COMMON, CONSOLIDATED UPDATED EU-RMP TEMPLATE, WHICH WAS BASED ON PUBLICATION OF GVP MODULE V REV.2 ON 30 MARCH 2017 AND WILL INCLUDE BOTH FORMULATIONS & INDICATIONS. - PROPOSING THE REMOVAL OF ALL IMPORTANT IDENTIFIED/POTENTIAL RISKS AND MISSING INFORMATION FROM BOTH PRIOR EURMPS IN LIGHT OF THE CHANGES TO THE SAFETY CONCERNS DEFINITIONS IN THE GVP V R2, AS WELL AS THE EXTENSIVE POST-MARKETING EXPERIENCE. - PROVISION OF RESULTS OF LONG-TERM SAFETY

										DATA FOR PARKINSON'S DISEASE (PD) WHICH WERE ONGOING AT THE TIME OF THE PD-PR EURMP SUBMISSION.
PL 19494/0036	ADARTREL 2 MG FILM-COATED TABLETS	GRANTED	PL 19494/0036-0074	PL 19494/0036-0074	14/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN COMPRISING FOLLOWING CHANGES: - COMBINATION OF THE TWO EXISTING ROPINIROLE EURMPS FORMAT (PD-PR V2, AND RLS-IR V2) INTO ONE COMMON, CONSOLIDATED UPDATED EU-RMP TEMPLATE, WHICH WAS BASED ON PUBLICATION OF GVP MODULE V REV.2 ON 30 MARCH 2017 AND WILL INCLUDE BOTH FORMULATIONS & INDICATIONS. - PROPOSING THE REMOVAL OF ALL IMPORTANT IDENTIFIED/POTENTIAL RISKS AND MISSING INFORMATION FROM BOTH PRIOR EURMPS IN LIGHT OF THE CHANGES TO THE SAFETY CONCERNS DEFINITIONS IN THE GVP V R2, AS WELL AS THE EXTENSIVE POST-MARKETING EXPERIENCE.

										- PROVISION OF RESULTS OF LONG-TERM SAFETY DATA FOR PARKINSON'S DISEASE (PD) WHICH WERE ONGOING AT THE TIME OF THE PD-PR EURMP SUBMISSION.
PL 08265/0026	SEVIKAR 20MG/5MG FILM-COATED TABLET	GRANTED	PL 08265/0026-0070	PL 08265/0026-0070	16/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND THE PIL AS PRESCRIBED BY THE ARTICLE 5 RECOMMENDATION DATED 28.06.2010 ON UPDATES TO COMBINATION PRODUCTS IN LINE WITH ONE OF THE MONOPRODUCTS.
PL 08265/0027	SEVIKAR 40MG/5MG FILM-COATED TABLETS	GRANTED	PL 08265/0027-0069	PL 08265/0027-0069	16/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND THE PIL AS PRESCRIBED BY THE ARTICLE 5 RECOMMENDATION DATED 28.06.2010 ON UPDATES TO COMBINATION PRODUCTS IN LINE WITH ONE OF THE MONOPRODUCTS.
PL 08265/0028	SEVIKAR 40MG/10MG FILM-COATED TABLETS	GRANTED	PL 08265/0028-0068	PL 08265/0028-0068	16/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND THE PIL AS PRESCRIBED BY THE ARTICLE 5 RECOMMENDATION DATED 28.06.2010 ON UPDATES TO COMBINATION PRODUCTS IN LINE WITH ONE OF THE MONOPRODUCTS.

PL 20075/1368	PIPERACILLIN/TAZOBACTAM 2 G/0.25 G POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 20075/1368-0011	PL 20075/1368-0011	21/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.1, 4.5, 4.6, 4.8, 5.1 AND 5.2 OF THE SMPC AND PIL IN-LINE WITH THE PRODUCT INFORMATION OF REFERENCE PRODUCT (TAZOCIN 2G/0.25G & 4 G / 0.5 G POWDER FOR SOLUTION FOR INFUSION WITH EU PROCEDURE NUMBER: IT/H/0675/001 AND MAH: PFIZER LIMITED) FOR PIPERACILLIN/TAZOBACTAM 2 G/0.25 G AND 4 G/0.5 G POWDER FOR SOLUTION FOR INFUSION
PL 20075/1369	PIPERACILLIN/TAZOBACTAM 4 G/0.5 G POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 20075/1369-0010	PL 20075/1369-0010	21/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.1, 4.5, 4.6, 4.8, 5.1 AND 5.2 OF THE SMPC AND PIL IN-LINE WITH THE PRODUCT INFORMATION OF REFERENCE PRODUCT (TAZOCIN 2G/0.25G & 4 G / 0.5 G POWDER FOR SOLUTION FOR INFUSION WITH EU PROCEDURE NUMBER: IT/H/0675/001 AND MAH: PFIZER LIMITED) FOR PIPERACILLIN/TAZOBACTAM 2 G/0.25 G AND 4 G/0.5 G POWDER FOR SOLUTION FOR INFUSION
PL 10949/0340	ZYBAN 150 MG PROLONGED RELEASE TABLETS	GRANTED	PL 10949/0340-0103	PL 10949/0340-0103	22/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC WITH THE ADVERSE EVENT DYSPHEMIA/STUTTERING.

								CMS WORKSHARING		CONSEQUENTLY, THE LEAFLET IS UPDATED.
PL 50414/0002	ATIONDO FILM-COATED TABLETS 75 MG	GRANTED	PL 50414/0002-0003	PL 50414/0002-0003	23/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE PRODUCT INFORMATION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS) IN SMPC SECTION 4.6 AND CORRESPONDING PATIENT INFORMATION LEAFLET (PIL) FOR ATIONDO FILM-COATED TABLETS AND ATIONDO SR PROLONGED-RELEASE TABLETS.
PL 50414/0003	ATIONDO FILM-COATED TABLETS 100 MG	GRANTED	PL 50414/0003-0003	PL 50414/0003-0003	23/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE PRODUCT INFORMATION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS) IN SMPC SECTION 4.6 AND CORRESPONDING PATIENT INFORMATION LEAFLET (PIL) FOR ATIONDO FILM-COATED TABLETS AND ATIONDO SR

										PROLONGED-RELEASE TABLETS.
PL 50414/0004	ATIONDO SR 25MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0004-0004	PL 50414/0004-0004	23/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	UPDATE THE PRODUCT INFORMATION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS) IN SMPC SECTION 4.6 AND CORRESPONDING PATIENT INFORMATION LEAFLET (PIL) FOR ATIONDO FILM-COATED TABLETS AND ATIONDO SR PROLONGED-RELEASE TABLETS.
PL 50414/0005	ATIONDO SR 50 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0005-0004	PL 50414/0005-0004	23/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	UPDATE THE PRODUCT INFORMATION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS) IN SMPC SECTION 4.6 AND CORRESPONDING PATIENT INFORMATION LEAFLET (PIL) FOR ATIONDO FILM-COATED TABLETS AND ATIONDO SR

										PROLONGED-RELEASE TABLETS.
PL 50414/0006	ATIONDO SR 100MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0006-0004	PL 50414/0006-0004	23/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	UPDATE THE PRODUCT INFORMATION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS) IN SMPC SECTION 4.6 AND CORRESPONDING PATIENT INFORMATION LEAFLET (PIL) FOR ATIONDO FILM-COATED TABLETS AND ATIONDO SR PROLONGED-RELEASE TABLETS.
PL 50414/0007	ATIONDO SR 150MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0007-0004	PL 50414/0007-0004	23/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	UPDATE THE PRODUCT INFORMATION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS) IN SMPC SECTION 4.6 AND CORRESPONDING PATIENT INFORMATION LEAFLET (PIL) FOR ATIONDO FILM-COATED TABLETS AND ATIONDO SR

										PROLONGED-RELEASE TABLETS.
PL 50414/0008	ATIONDO SR 200MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0008-0004	PL 50414/0008-0004	23/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	UPDATE THE PRODUCT INFORMATION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS) IN SMPC SECTION 4.6 AND CORRESPONDING PATIENT INFORMATION LEAFLET (PIL) FOR ATIONDO FILM-COATED TABLETS AND ATIONDO SR PROLONGED-RELEASE TABLETS.
PL 50414/0009	ATIONDO SR 250MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0009-0004	PL 50414/0009-0004	23/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	UPDATE THE PRODUCT INFORMATION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS) IN SMPC SECTION 4.6 AND CORRESPONDING PATIENT INFORMATION LEAFLET (PIL) FOR ATIONDO FILM-COATED TABLETS AND ATIONDO SR

										PROLONGED-RELEASE TABLETS.
PL 02855/0076	PANADOL COLD & SINUS	GRANTED	PL 02855/0076-0017	PL 02855/0076-0017	24/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4 AND 5.3 OF THE SMPC.
PL 02855/0076	PANADOL COLD & SINUS	GRANTED	PL 02855/0076-0017	PL 02855/0076-0017	24/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4 AND 5.3 OF THE SMPC.
PL 11587/0043	EPIRUBICIN HYDROCHLORIDE 2 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 11587/0043-0040	PL 11587/0043-0040	26/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATED SECTIONS 4.4, 4.5 AND 4.8 OF THE SMPC AND PIL IN LINE WITH THE PROCEDURE AT/H/XXXX/WS/078 AND PROCEDURE DK/H/XXXX/WS/055 FOR DE/H/0807/001/DC. TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6 AND 4.9 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT FARMORUBICIN, PULVER ZUR HERSTELLUNG EINER INJEKTIONSLÖSUNG PFIZER.

PL 14894/0159	CLARITHROMYCIN 250MG FILM-COATED TABLETS	GRANTED	PL 14894/0159-0074	PL 14894/0159-0074	27/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER UPDATES TO SECTIONS 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 5.2, 5.3 AND 6.5 OF THE SPC TO BRING IN LINE WITH REFERENCE PRODUCT KLACID 250 MG AND 500 MG, TABLETKI POWLEKANE, MAH: MYLAN HEALTHCARE SP. Z O.O., MA NUMBERS: 03318, 07194. CONSEQUENTIALLY THE PIL TEXT HAS BEEN UPDATED.
PL 14894/0160	CLARITHROMYCIN 500MG FILM-COATED TABLETS	GRANTED	PL 14894/0160-0070	PL 14894/0160-0070	27/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER UPDATES TO SECTIONS 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 5.2, 5.3 AND 6.5 OF THE SPC TO BRING IN LINE WITH REFERENCE PRODUCT KLACID 250 MG AND 500 MG, TABLETKI POWLEKANE, MAH: MYLAN HEALTHCARE SP. Z O.O., MA NUMBERS: 03318, 07194. CONSEQUENTIALLY THE PIL TEXT HAS BEEN UPDATED.
PL 18024/0009	SATIVEX OROMUCOSAL SPRAY	GRANTED	PL 18024/0009-0068	PL 18024/0009-0068	27/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO REGISTER AN UPDATE TO THE RMP FROM V3.0 TO V3.1, IN LINE WITH THE NEW FORMAT ACCORDING TO THE NEW REV. 2 OF GVP MODULE V AND THE OUTCOME OF

										THE DISCUSSION IN THIS PSUR ABOUT THE REGISTRY STUDY (THE RESPONSES TO THE PSUR REVIEW ARE INCLUDED IN ADDITIONAL DATA).
PL 36633/0009	OCTASA 1600MG MODIFIED-RELEASE TABLETS	GRANTED	PL 36633/0009-0012	PL 36633/0009-0012	29/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL FOLLOWING ASSESSMENT OF THE SAME CHANGE FOR THE REFERENCE PRODUCT
PL 04425/0651	SOLIAN 100MG TABLETS	GRANTED	PL 04425/0651-0066	PL 04425/0651-0066	30/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0652	SOLIAN 200MG TABLETS	GRANTED	PL 04425/0652-0063	PL 04425/0652-0063	30/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0653	SOLIAN 400MG FILM-COATED TABLETS	GRANTED	PL 04425/0653-0064	PL 04425/0653-0064	30/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET

								RD) - CMS WORKSHARING		(CCDS). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0654	SOLIAN 100MG/ML SOLUTION	GRANTED	PL 04425/0654-0056	PL 04425/0654-0056	30/09/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 08081/0040	MEZAVANT XL 1200MG, GASTRO-RESISTANT, PROLONGED RELEASE TABLETS	GRANTED	PL 08081/0040-0050	PL 08081/0040-0050	05/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.6, 4.8, 5.1 AND 5.2 OF THE SMPC FRAGMENTS IN LINE WITH THE RECENT UPDATE TO SHIRE'S COMPANY CORE DATA SHEET (CCDS) VERSION 23.0 AND PRAC RECOMMENDATIONS ON PROCEDURE NO.: PSUSA/00001990/202002. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50827/0002	SEROQUEL 25 MG FILM-COATED TABLETS	GRANTED	PL 50827/0002-0020	PL 50827/0002-0020	05/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC FOLLOWING THE UPDATE OF THE COMPANY CORE DATA SHEET. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

								WORKSHARING		
PL 50827/0003	SEROQUEL 100 MG FILM-COATED TABLETS	GRANTED	PL 50827/0003-0019	PL 50827/0003-0019	05/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC FOLLOWING THE UPDATE OF THE COMPANY CORE DATA SHEET. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 50827/0004	SEROQUEL 200 MG FILM-COATED TABLETS	GRANTED	PL 50827/0004-0021	PL 50827/0004-0021	05/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC FOLLOWING THE UPDATE OF THE COMPANY CORE DATA SHEET. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 50827/0005	SEROQUEL 300 MG FILM-COATED TABLETS	GRANTED	PL 50827/0005-0021	PL 50827/0005-0021	05/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC FOLLOWING THE UPDATE OF THE COMPANY CORE DATA SHEET. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 50827/0006	SEROQUEL XL 50 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50827/0006-0030	PL 50827/0006-0030	05/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC FOLLOWING THE UPDATE OF THE COMPANY CORE DATA SHEET. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 50827/0007	SEROQUEL XL 150MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50827/0007-0028	PL 50827/0007-0028	05/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC FOLLOWING THE UPDATE OF THE COMPANY CORE

								RD) - CMS WORKSHARING		DATA SHEET. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 50827/0008	SEROQUEL XL 200 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50827/0008-0029	PL 50827/0008-0029	05/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC FOLLOWING THE UPDATE OF THE COMPANY CORE DATA SHEET. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 50827/0009	SEROQUEL XL 300 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50827/0009-0029	PL 50827/0009-0029	05/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC FOLLOWING THE UPDATE OF THE COMPANY CORE DATA SHEET. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 50827/0010	SEROQUEL XL 400 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50827/0010-0030	PL 50827/0010-0030	05/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC FOLLOWING THE UPDATE OF THE COMPANY CORE DATA SHEET. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00025/0563	NEXPLANON 68MG IMPLANT FOR SUBDERMAL USE	GRANTED	PL 00025/0563-0055	PL 00025/0563-0055	06/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND CORRESPONDING SECTION 2 OF THE PIL WITH THE INFORMATION CONCERNING BROKEN OR BENT IMPLANT AVAILABLE FROM POST-MARKETING REPORTS ABOUT EVENTS OF IMPLANT BREAKAGE RELATED TO THE

										MANIPULATION OR TRAUMA TO THE IMPLANT SITE AND IMPLANT MIGRATION AFTER BREAKAGE AND SECTION 4.2, 4.3, 4.6, 4.8, 5.2, 6.1 AND 6.5 OF THE SMPC, LABELLING AND PIL IN LINE WITH THE QRD TEMPLATE. ADDITIONALLY, THE MAH HAS USED THIS OPPORTUNITY TO UPDATE THE DETAILS OF THE LOCAL REPRESENTATIVE.
PL 20011/0072	ANGUSTA 25 MICROGRAM TABLETS	GRANTED	PL 20011/0072-0007	PL 20011/0072-0007	06/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.6 OF THE SMPC, LABELLING AND RELATED SECTIONS OF THE PIL IN LINE WITH THE COMMENTS RECEIVED REPEAT USE PROCEDURE (RUP) DK/H/2584/001/E/002,
PL 44673/0153	OTRIVINE EXTRA DUAL RELIEF 0.5MG/ML, 0.6MG/ML NASAL SPRAY	GRANTED	PL 44673/0153-0034	PL 44673/0153-0034	06/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE THE SPC SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8 AND 5.3 (AND CONSEQUENTIALLY THE PIL) TO DEFINE THE COMPANY POSITION AND REFERENCE SAFETY INFORMATION FOR ALL IPRATROPIUM BROMIDE AND XYLOMETAZOLINE HYDROCHLORIDE MAS - THIS FOLLOWS A JOINT VENTURE BETWEEN GSK CH AND NCH.

										THE UPDATE FROM MRP SE/H/0848/001/IA/070, IMPLEMENTING THE PRAC RECOMMENDATION (EMA/PRAC/12854/2021) FOR XYLOMETAZOLINE-CONTAINING PRODUCTS TO ADD 'EPISTAXIS' WITH A FREQUENCY OF 'UNCOMMON' TO THE PI, IS ALSO INCLUDED - SEE 'INPUT' FOLDER FOR THE ACKNOWLEDGEMENT OF AN ACCEPTABLE NOTIFICATION FROM THE RMS, DATED 05/07/2021.
PL 21039/0009	BETESIL MEDICATED PLASTER 2.25MG	GRANTED	PL 21039/0009-0042	PL 21039/0009-0042	07/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.1, 4.3, 4.6 AND 5.3 OF THE SMPC ACCORDING TO THE Q 3.9 PROVIDED IN THE ¿Q/A - LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008¿ (CMDH/132/2009/REV.54 SEPTEMBER 2019),
PL 34777/0001	CAPTOPRIL 5 MG/5 ML ORAL SOLUTION	GRANTED	PL 34777/0001-0029	PL 34777/0001-0029	07/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO UPDATE THE RMP FROM VERSION 1.0 (JULY 2017) TO VERSION 1.12 (APRIL 2021), TO UPDATE TO THE CURRENT FORMAT AND FOLLOWING THE OUTCOME OF THE RECENT PSUR FOR CAPTOPRIL, AND THE RESULTING UPDATES MADE TO THE PRODUCT

										INFORMATION (VARIATION IE/H/0837/001-002/IB/013) IN ACCORDANCE WITH PSUSA/00000535/202004.
PL 34777/0002	CAPTOPRIL 25 MG/5 ML ORAL SOLUTION	GRANTED	PL 34777/0002-0026	PL 34777/0002-0026	07/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO UPDATE THE RMP FROM VERSION 1.0 (JULY 2017) TO VERSION 1.12 (APRIL 2021), TO UPDATE TO THE CURRENT FORMAT AND FOLLOWING THE OUTCOME OF THE RECENT PSUR FOR CAPTOPRIL, AND THE RESULTING UPDATES MADE TO THE PRODUCT INFORMATION (VARIATION IE/H/0837/001-002/IB/013) IN ACCORDANCE WITH PSUSA/00000535/202004.
PL 00242/0301	TOPAMAX 25 MG FILM-COATED TABLETS	GRANTED	PL 00242/0301-0159	PL 00242/0301-0159	11/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.1 OF THE SPC, ADDING INFORMATION ON GROWTH, DEVELOPMENT, AND BONE MINERALIZATION IN PAEDIATRIC PATIENTS WITH NEW OR RECENT EPILEPSY, BASED ON RESULTS OF CLINICAL STUDY- CSR TOPMATEPY4067 UNDERTAKEN AT THE REQUEST OF THE US FDA. TO ALSO UPDATE SECTION 4.4 TO INCLUDE A CROSS-REFERENCE TO THE NEW INFORMATION IN SECTION 5.1. MINOR EDITORIAL UPDATES ARE

										ALSO MADE THROUGHOUT THE SPC AND PIL.
PL 00242/0302	TOPAMAX 50 MG FILM-COATED TABLETS	GRANTED	PL 00242/0302-0160	PL 00242/0302-0160	11/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.1 OF THE SPC, ADDING INFORMATION ON GROWTH, DEVELOPMENT, AND BONE MINERALIZATION IN PAEDIATRIC PATIENTS WITH NEW OR RECENT EPILEPSY, BASED ON RESULTS OF CLINICAL STUDY- CSR TOPMATEPY4067 UNDERTAKEN AT THE REQUEST OF THE US FDA. TO ALSO UPDATE SECTION 4.4 TO INCLUDE A CROSS-REFERENCE TO THE NEW INFORMATION IN SECTION 5.1. MINOR EDITORIAL UPDATES ARE ALSO MADE THROUGHOUT THE SPC AND PIL.
PL 00242/0303	TOPAMAX 100 MG FILM-COATED TABLETS	GRANTED	PL 00242/0303-0161	PL 00242/0303-0161	11/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.1 OF THE SPC, ADDING INFORMATION ON GROWTH, DEVELOPMENT, AND BONE MINERALIZATION IN PAEDIATRIC PATIENTS WITH NEW OR RECENT EPILEPSY, BASED ON RESULTS OF CLINICAL STUDY- CSR TOPMATEPY4067 UNDERTAKEN AT THE

										REQUEST OF THE US FDA. TO ALSO UPDATE SECTION 4.4 TO INCLUDE A CROSS-REFERENCE TO THE NEW INFORMATION IN SECTION 5.1. MINOR EDITORIAL UPDATES ARE ALSO MADE THROUGHOUT THE SPC AND PIL.
PL 00242/0304	TOPAMAX 200 MG FILM-COATED TABLETS	GRANTED	PL 00242/0304-0159	PL 00242/0304-0159	11/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.1 OF THE SPC, ADDING INFORMATION ON GROWTH, DEVELOPMENT, AND BONE MINERALIZATION IN PAEDIATRIC PATIENTS WITH NEW OR RECENT EPILEPSY, BASED ON RESULTS OF CLINICAL STUDY- CSR TOPMATEPY4067 UNDERTAKEN AT THE REQUEST OF THE US FDA. TO ALSO UPDATE SECTION 4.4 TO INCLUDE A CROSS-REFERENCE TO THE NEW INFORMATION IN SECTION 5.1. MINOR EDITORIAL UPDATES ARE ALSO MADE THROUGHOUT THE SPC AND PIL.
PL 00242/0348	TOPAMAX SPRINKLE 15 MG HARD CAPSULES	GRANTED	PL 00242/0348-0137	PL 00242/0348-0137	11/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.1 OF THE SPC, ADDING INFORMATION ON GROWTH, DEVELOPMENT, AND BONE MINERALIZATION IN

										PAEDIATRIC PATIENTS WITH NEW OR RECENT EPILEPSY, BASED ON RESULTS OF CLINICAL STUDY- CSR TOPMATEPY4067 UNDERTAKEN AT THE REQUEST OF THE US FDA. TO ALSO UPDATE SECTION 4.4 TO INCLUDE A CROSS-REFERENCE TO THE NEW INFORMATION IN SECTION 5.1. MINOR EDITORIAL UPDATES ARE ALSO MADE THROUGHOUT THE SPC AND PIL.
PL 00242/0349	TOPAMAX SPRINKLE 25 MG HARD CAPSULES	GRANTED	PL 00242/0349-0139	PL 00242/0349-0139	11/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.1 OF THE SPC, ADDING INFORMATION ON GROWTH, DEVELOPMENT, AND BONE MINERALIZATION IN PAEDIATRIC PATIENTS WITH NEW OR RECENT EPILEPSY, BASED ON RESULTS OF CLINICAL STUDY- CSR TOPMATEPY4067 UNDERTAKEN AT THE REQUEST OF THE US FDA. TO ALSO UPDATE SECTION 4.4 TO INCLUDE A CROSS-REFERENCE TO THE NEW INFORMATION IN SECTION 5.1. MINOR EDITORIAL UPDATES ARE ALSO MADE

										THROUGHOUT THE SPC AND PIL.
PL 00242/0350	TOPAMAX SPRINKLE 50 MG HARD CAPSULES	GRANTED	PL 00242/0350-0137	PL 00242/0350-0137	11/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.1 OF THE SPC, ADDING INFORMATION ON GROWTH, DEVELOPMENT, AND BONE MINERALIZATION IN PAEDIATRIC PATIENTS WITH NEW OR RECENT EPILEPSY, BASED ON RESULTS OF CLINICAL STUDY- CSR TOPMATEPY4067 UNDERTAKEN AT THE REQUEST OF THE US FDA. TO ALSO UPDATE SECTION 4.4 TO INCLUDE A CROSS-REFERENCE TO THE NEW INFORMATION IN SECTION 5.1. MINOR EDITORIAL UPDATES ARE ALSO MADE THROUGHOUT THE SPC AND PIL.
PL 28176/0177	IBUPROFEN LYSINE 342 MG FILM-COATED TABLETS	GRANTED	PL 28176/0177-0007	PL 28176/0177-0007	12/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, NUROFEN EXPRESS. [2] TO UPDATE SECTIONS 4.8 AND 4.9 OF THE SMPC IN LINE WITH THE PSUSA (EMA - PSUSA/00010345/201702 - DATED 30 NOVEMBER

										2017). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 28176/0177	IBUPROFEN LYSINE 342 MG FILM-COATED TABLETS	GRANTED	PL 28176/0177-0007	PL 28176/0177-0007	12/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, NUROFEN EXPRESS. [2] TO UPDATE SECTIONS 4.8 AND 4.9 OF THE SMPC IN LINE WITH THE PSUSA (EMA - PSUSA/00010345/201702 - DATED 30 NOVEMBER 2017). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 28176/0178	IBUPROFEN LYSINE 684 MG FILM-COATED TABLETS	GRANTED	PL 28176/0178-0007	PL 28176/0178-0007	12/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, NUROFEN EXPRESS. [2] TO UPDATE SECTIONS 4.8 AND 4.9 OF THE SMPC IN LINE WITH THE PSUSA (EMA - PSUSA/00010345/201702 - DATED 30 NOVEMBER 2017). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 28176/0178	IBUPROFEN LYSINE 684 MG FILM-COATED TABLETS	GRANTED	PL 28176/0178-0007	PL 28176/0178-0007	12/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, NUROFEN EXPRESS. [2] TO UPDATE SECTIONS 4.8 AND 4.9 OF THE SMPC IN LINE WITH THE PSUSA (EMA - PSUSA/00010345/201702 - DATED 30 NOVEMBER 2017). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 41809/0001	ANATERA 100 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 41809/0001-0018	PL 41809/0001-0018	14/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC IN LINE WITH INFORMATION FROM LITERATURE ON CONTRAST-INDUCED NEPHROPATHY FOLLOWING FLUORESCEIN ANGIOGRAPHY (FA). ADDITIONAL UPDATES HAVE BEEN MADE IN LINE WITH EU COMMISSION EXCIPIENTS GUIDANCE ON "EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE (SANTE-2017-11668) AND THE CURRENT QRD TEMPLATE.

										CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 18992/0001	PULMOTEC	GRANTED	PL 18992/0001-0035	PL 18992/0001-0035	19/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO ADD TO THE DOSSIER THE RECOMMENDED ELEMENTS MENTIONED IN THE PARAGRAPH 4.12 OF THE Q&A - LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008, REV50, JULY 2018 (MRP, ERA, UPDATED SUMMARY OF PSMF, ¿.) RMP: THE RISK MANAGEMENT PLAN (RMP) HAS BEEN ADDED IN THE SECTION 1.8.1 OF THE DOSSIER. 2. TO PRESENT A PARTIALLY REWRITTEN AND REFORMATTED MODULE 3 BASED UPON THE ACTUAL GUIDELINES APPLICABLE TO RADIOPHARMACEUTICALS. A NEW QUALITY OVERAL SUMMARY (SECTION 2.3) HAS BEEN CONSEQUENTLY WRITTEN. 3.TO ADD ADDITIONAL REFERENCES TO THE

										MODULE 4, WITH CONSEQUENT UPDATE OF THE NON CLINICAL OVERVIEW (SECTION 2.4). 4.TO UPDATE SECTIONS 4.2, 4.6 AND 4.8 OF THE SMPC BASED UPON THE ADDITION OF NEW REFERENCES TO THE MODULE 5 AND CONSEQUENT UPDATE OF THE CLINICAL OVERVIEW (2.5).
PL 18992/0001	PULMOTEC	GRANTED	PL 18992/0001-0035	PL 18992/0001-0035	19/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO ADD TO THE DOSSIER THE RECOMMENDED ELEMENTS MENTIONED IN THE PARAGRAPH 4.12 OF THE Q&A - LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008, REV50, JULY 2018 (MRP, ERA, UPDATED SUMMARY OF PSMF, ¿.) RMP: THE RISK MANAGEMENT PLAN (RMP) HAS BEEN ADDED IN THE SECTION 1.8.1 OF THE DOSSIER. 2. TO PRESENT A PARTIALLY REWRITTEN AND REFORMATTED MODULE 3 BASED UPON

										THE ACTUAL GUIDELINES APPLICABLE TO RADIOPHARMACEUTICALS. A NEW QUALITY OVERAL SUMMARY (SECTION 2.3) HAS BEEN CONSEQUENTLY WRITTEN. 3.TO ADD ADDITIONAL REFERENCES TO THE MODULE 4, WITH CONSEQUENT UPDATE OF THE NON CLINICAL OVERVIEW (SECTION 2.4). 4.TO UPDATE SECTIONS 4.2, 4.6 AND 4.8 OF THE SMPC BASED UPON THE ADDITION OF NEW REFERENCES TO THE MODULE 5 AND CONSEQUENT UPDATE OF THE CLINICAL OVERVIEW (2.5).
PL 00038/0105	AMOXIL CAPSULES 500MG	GRANTED	PL 00038/0105-0110	PL 00038/0105-0110	27/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1. TO ADD 'ASEPTIC MENINGITIS' TO SECTION 4.8 OF THE SPC. 2. TO ENSURE 'DRESS SYNDROME IS ADDED TO SECTION 4.8 OF THE SPC. 3. *TO UPDATE THE EXCIPIENTS INFORMATION FOR SODIUM IN SECTION 4.4 OF THE SPC IN LINE WITH THE LATEST EU

										EXCIPIENT GUIDELINE. 4. *TO REVISE THE DOSE IN CHILDREN WITH LYME DISEASE IN SECTION 4.2 OF THE SPC FROM 100MG/KG TO 50MG/KG BODY WEIGHT. CONSEQUENTIALLY, THE PIL TEXT HAS BEEN UPDATED. *CHANGES APPLY TO INJECTION ONLY ---------- ***PIL TEXT FOR CAPSULES NOT SUBMITTED AS THIS ALREADY INCLUDES THE RELEVANT INFORMATION ON ASEPTIC MENINGITIS AND DRESS.
PL 00038/0105	AMOXIL CAPSULES 500MG	GRANTED	PL 00038/0105-0110	PL 00038/0105-0110	27/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1. TO ADD 'ASEPTIC MENINGITIS' TO SECTION 4.8 OF THE SPC. 2. TO ENSURE 'DRESS SYNDROME IS ADDED TO SECTION 4.8 OF THE SPC. 3. *TO UPDATE THE EXCIPIENTS INFORMATION FOR SODIUM IN SECTION 4.4 OF THE SPC IN LINE WITH

										THE LATEST EU EXCIPIENT GUIDELINE. 4. *TO REVISE THE DOSE IN CHILDREN WITH LYME DISEASE IN SECTION 4.2 OF THE SPC FROM 100MG/KG TO 50MG/KG BODY WEIGHT. CONSEQUENTIALLY, THE PIL TEXT HAS BEEN UPDATED. *CHANGES APPLY TO INJECTION ONLY ---------- ***PIL TEXT FOR CAPSULES NOT SUBMITTED AS THIS ALREADY INCLUDES THE RELEVANT INFORMATION ON ASEPTIC MENINGITIS AND DRESS.
PL 00289/0973	AZITHROMYCIN 200MG/5ML POWDER FOR SUSPENSION	GRANTED	PL 00289/0973-0058	PL 00289/0973-0058	29/10/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.1 AND 6.6 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, ZITHROMAX® (MAH: PFIZER BV). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD

										TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 16853/0149	VARIQUEL 0.2MG/ML SOLUTION FOR INJECTION	GRANTED	PL 16853/0149-0013	PL 16853/0149-0013	02/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.3, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SMPC AND PIL WITH THE REFERENCE PRODUCT INFORMATION AND IN LINE WITH THE QRD TEMPLATE.
PL 03551/0120	GELASPAN SOLUTION FOR INFUSION	GRANTED	PL 03551/0120-0036	PL 03551/0120-0036	03/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.3, 4.4 AND 4.9 OF THE SPC TO BRING IN LINE WITH COMPANY CORE DATA SHEET UPDATE BASED ON LITERATURE INVESTIGATIONS FOLLOWED BY A COMPREHENSIVE REVISION OF THE CLINICAL OVERVIEW AND NON-CLINICAL OVERVIEW IN ORDER TO REFLECT CURRENT STATE OF SCIENTIFIC KNOWLEDGE.
PL 03551/0120	GELASPAN SOLUTION FOR INFUSION	GRANTED	PL 03551/0120-0037	PL 03551/0120-0037	03/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS)
PL 03551/0120	GELASPAN SOLUTION FOR INFUSION	GRANTED	PL 03551/0120-0039	PL 03551/0120-0039	03/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 5.1, 5.2, 5.3 AND OF THE SMPC AND CONSEQUENTIALLY THE PIL TO ADAPT TO AN UPDATED COMPANY

										CORE DATA SHEET (CCDS). CHANGES INVOLVED: 1. MODIFICATION OF AN APPROVED THERAPEUTIC INDICATION 2. ADDITION OF ACUTE CONGESTIVE HEART FAILURE AS CONTRAINDICATION 3. PRECAUTIONS IN THE USE OF GELASPAN IN CASE OF HYPOVOLAEMIA
PL 03551/0120	GELASPAN SOLUTION FOR INFUSION	GRANTED	PL 03551/0120-0039	PL 03551/0120-0039	03/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 5.1, 5.2, 5.3 AND OF THE SMPC AND CONSEQUENTIALLY THE PIL TO ADAPT TO AN UPDATED COMPANY CORE DATA SHEET (CCDS). CHANGES INVOLVED: 1. MODIFICATION OF AN APPROVED THERAPEUTIC INDICATION 2. ADDITION OF ACUTE CONGESTIVE HEART FAILURE AS CONTRAINDICATION 3. PRECAUTIONS IN THE USE OF GELASPAN IN CASE OF HYPOVOLAEMIA

PL 29831/0356	AMITRIPTYLINE HYDROCHLORIDE 25MG/5ML ORAL SOLUTION	GRANTED	PL 29831/0356-0031	PL 29831/0356-0031	03/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE SPC (4.8) TO INCLUDE 'ANAPHYLAXIS' & 'ANGIOEDEMA' (FREQUENCY ¿NOT KNOWN¿) AND RELOCATE 'FACE OEDEMA' & 'TONGUE OEDEMA' (FREQUENCY "UNCOMMON") TO THE SOC 'IMMUNE SYSTEM DISORDERS', AS PER THE MHRA¿S REQUEST FOLLOWING A SIGNAL ASSESSMENT FOR AMITRIPTYLINE. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED. FURTHERMORE, THE UK LABELLING HAS ALSO BEEN REVISED TO REMOVE INFORMATION RELATING TO IRELAND & MALTA, FOLLOWING THE END OF THE BREXIT TRANSITION PERIOD.
PL 29831/0439	AMITRIPTYLINE HYDROCHLORIDE 50MG/5ML ORAL SOLUTION	GRANTED	PL 29831/0439-0033	PL 29831/0439-0033	03/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE SPC (4.8) TO INCLUDE 'ANAPHYLAXIS' & 'ANGIOEDEMA' (FREQUENCY ¿NOT KNOWN¿) AND RELOCATE 'FACE OEDEMA' & 'TONGUE OEDEMA' (FREQUENCY "UNCOMMON") TO THE SOC 'IMMUNE SYSTEM DISORDERS', AS PER THE MHRA¿S REQUEST

										FOLLOWING A SIGNAL ASSESSMENT FOR AMITRIPTYLINE. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED. FURTHERMORE, THE UK LABELLING HAS ALSO BEEN REVISED TO REMOVE INFORMATION RELATING TO IRELAND & MALTA, FOLLOWING THE END OF THE BREXIT TRANSITION PERIOD.
PL 51419/0001	DULCOBALANCE 10G, POWDER FOR ORAL SOLUTION IN SACHET	GRANTED	PL 51419/0001-0009	PL 51419/0001-0009	03/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SPC SECTION 4.4 AND PIL SECTION 2, IN LINE WITH THE CCDS V1.0 (14/05/2020) TO INCLUDE A CAUTION FOR USE WARNING IN PATIENTS WITH IMPAIRED GAG REFLEX AND PATIENTS PRONE TO REGURGITATION OR ASPIRATION. ALSO, TO MAKE EDITORIAL / QRD / EXCIPIENT UPDATES TO THE SPC SECTIONS 2, 4.2, 4.4, 4.6, 4.7, 4.8, 4.9, 6.1, 6.6, 7 & PIL.
PL 16363/0479	NAPROXEN 250 MG TABLETS	GRANTED	PL 16363/0479-0020	PL 16363/0479-0020	04/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.6, 4.7, 4.8, 4.9. 5.1, 5.2, 6.6 OF THE SMPC AND PIL FOR NAPROXEN 250 MG AND 500 MG TABLETS IN LINE WITH THE REFERENCE PRODUCT NAPROSYN 500MG TABLETS BY MAH

										ATNAHS PHARMA UK LIMITED.
PL 16363/0480	NAPROXEN 500 MG TABLETS	GRANTED	PL 16363/0480-0020	PL 16363/0480-0020	04/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.6, 4.7, 4.8, 4.9. 5.1, 5.2, 6.6 OF THE SMPC AND PIL FOR NAPROXEN 250 MG AND 500 MG TABLETS IN LINE WITH THE REFERENCE PRODUCT NAPROSYN 500MG TABLETS BY MAH ATNAHS PHARMA UK LIMITED.
PL 48804/0001	OXYPRO 5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0001-0016	PL 48804/0001-0016	04/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2.0, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.3 AND 6.4 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT OXYGESIC 5 MG, 10 MG, 20 MG, 40, MG AND 80 MG RETARDTABLETTEN.
PL 48804/0002	OXYPRO 10 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0002-0017	PL 48804/0002-0017	04/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2.0, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.3 AND 6.4 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT OXYGESIC 5 MG, 10 MG, 20 MG, 40, MG AND 80 MG RETARDTABLETTEN.
PL 48804/0003	OXYPRO 15 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0003-0016	PL 48804/0003-0016	04/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2.0, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.3 AND 6.4 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT OXYGESIC 5 MG, 10 MG, 20

										MG, 40, MG AND 80 MG RETARDTABLETTEN.
PL 48804/0004	OXYPRO 20 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0004-0016	PL 48804/0004-0016	04/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2.0, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.3 AND 6.4 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT OXYGESIC 5 MG, 10 MG, 20 MG, 40, MG AND 80 MG RETARDTABLETTEN.
PL 48804/0005	OXYPRO 30 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0005-0017	PL 48804/0005-0017	04/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2.0, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.3 AND 6.4 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT OXYGESIC 5 MG, 10 MG, 20 MG, 40, MG AND 80 MG RETARDTABLETTEN.
PL 48804/0006	OXYPRO 40 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0006-0016	PL 48804/0006-0016	04/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2.0, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.3 AND 6.4 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT OXYGESIC 5 MG, 10 MG, 20 MG, 40, MG AND 80 MG RETARDTABLETTEN.
PL 48804/0007	OXYPRO 60 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0007-0018	PL 48804/0007-0018	04/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2.0, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.3 AND 6.4 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT OXYGESIC 5 MG, 10 MG, 20 MG, 40, MG AND 80 MG RETARDTABLETTEN.

PL 48804/0008	OXYPRO 80 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0008-0021	PL 48804/0008-0021	04/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2.0, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.3 AND 6.4 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT OXYGESIC 5 MG, 10 MG, 20 MG, 40, MG AND 80 MG RETARDTABLETTEN.
PL 12288/0011	TECHNESCAN DTPA 20.8 MG, KIT FOR RADIOPHARMACEUTICAL PREPARATION	GRANTED	PL 12288/0011-0011	PL 12288/0011-0011	07/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 6.1, 6.3, 6.4, 6.6, 11 AND 12 OF THE SPC TO BE CONSISTENT WITH THE RELEVANT INFORMATION IN QUALITY, CLINICAL AND PHARMACOVIGILANCE DATA FOR THE MEDICINAL PRODUCT TECHNESCAN DTPA. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED. ADDITIONALLY, THE PRODUCT INFORMATION HAS BEEN UPDATED IN LINE WITH GUIDELINE ON CORE SMPC AND PACKAGE LEAFLET FOR RADIOPHARMACEUTICALS (09/2011), EMA QRD TEMPLATE VERSION 10 (02/2016), ICRP PUBLICATION 128 ON

										RADIATION DOSE TO PATIENTS FROM RADIOPHARMACEUTICALS : A COMPENDIUM OF CURRENT INFORMATION RELATED TO FREQUENTLY USED SUBSTANCES (07/2014), EANM PEDIATRIC DOSAGE CARD (CURRENT VERSION).
PL 50414/0001	ATIONDO FILM-COATED TABLETS 50 MG	GRANTED	PL 50414/0001-0002	PL 50414/0001-0002	10/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.2, 4.4, 4.5, 4.6, 5.1 AND 6.1 OF THE SMPC FRAGMENTS IN ORDER TO HARMONIZE THE PRODUCT INFORMATION OF TAPENTADOL LIBRA-PHARM FILM-COATED TABLETS AND TAPENTADOL LIBRA-PHARM PROLONGED RELEASE TABLETS WITH THE QRD AND SPC GUIDELINES. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0002	ATIONDO FILM-COATED TABLETS 75 MG	GRANTED	PL 50414/0002-0002	PL 50414/0002-0002	10/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.2, 4.4, 4.5, 4.6, 5.1 AND 6.1 OF THE SMPC FRAGMENTS IN ORDER TO HARMONIZE THE PRODUCT INFORMATION OF TAPENTADOL LIBRA-PHARM FILM-COATED TABLETS AND TAPENTADOL LIBRA-PHARM PROLONGED

										RELEASE TABLETS WITH THE QRD AND SPC GUIDELINES. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0003	ATIONDO FILM-COATED TABLETS 100 MG	GRANTED	PL 50414/0003-0002	PL 50414/0003-0002	10/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.2, 4.4, 4.5, 4.6, 5.1 AND 6.1 OF THE SMPC FRAGMENTS IN ORDER TO HARMONIZE THE PRODUCT INFORMATION OF TAPENTADOL LIBRA-PHARM FILM-COATED TABLETS AND TAPENTADOL LIBRA-PHARM PROLONGED RELEASE TABLETS WITH THE QRD AND SPC GUIDELINES. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0004	ATIONDO SR 25MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0004-0003	PL 50414/0004-0003	10/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.2, 4.4, 4.5, 4.6, 5.1 AND 6.1 OF THE SMPC FRAGMENTS IN ORDER TO HARMONIZE THE PRODUCT INFORMATION OF TAPENTADOL LIBRA-PHARM FILM-COATED TABLETS AND TAPENTADOL LIBRA-PHARM PROLONGED RELEASE TABLETS WITH THE QRD AND SPC GUIDELINES.

										CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0005	ATIONDO SR 50 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0005-0003	PL 50414/0005-0003	10/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.2, 4.4, 4.5, 4.6, 5.1 AND 6.1 OF THE SMPC FRAGMENTS IN ORDER TO HARMONIZE THE PRODUCT INFORMATION OF TAPENTADOL LIBRA-PHARM FILM-COATED TABLETS AND TAPENTADOL LIBRA-PHARM PROLONGED RELEASE TABLETS WITH THE QRD AND SPC GUIDELINES. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0006	ATIONDO SR 100MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0006-0003	PL 50414/0006-0003	10/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.2, 4.4, 4.5, 4.6, 5.1 AND 6.1 OF THE SMPC FRAGMENTS IN ORDER TO HARMONIZE THE PRODUCT INFORMATION OF TAPENTADOL LIBRA-PHARM FILM-COATED TABLETS AND TAPENTADOL LIBRA-PHARM PROLONGED RELEASE TABLETS WITH THE QRD AND SPC GUIDELINES. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.

PL 50414/0007	ATIONDO SR 150MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0007-0003	PL 50414/0007-0003	10/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.2, 4.4, 4.5, 4.6, 5.1 AND 6.1 OF THE SMPC FRAGMENTS IN ORDER TO HARMONIZE THE PRODUCT INFORMATION OF TAPENTADOL LIBRA-PHARM FILM-COATED TABLETS AND TAPENTADOL LIBRA-PHARM PROLONGED RELEASE TABLETS WITH THE QRD AND SPC GUIDELINES. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0008	ATIONDO SR 200MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0008-0003	PL 50414/0008-0003	10/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.2, 4.4, 4.5, 4.6, 5.1 AND 6.1 OF THE SMPC FRAGMENTS IN ORDER TO HARMONIZE THE PRODUCT INFORMATION OF TAPENTADOL LIBRA-PHARM FILM-COATED TABLETS AND TAPENTADOL LIBRA-PHARM PROLONGED RELEASE TABLETS WITH THE QRD AND SPC GUIDELINES. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0009	ATIONDO SR 250MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0009-0003	PL 50414/0009-0003	10/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.2, 4.4, 4.5, 4.6, 5.1 AND 6.1 OF THE SMPC FRAGMENTS IN ORDER TO HARMONIZE THE

								RD) - CMS		PRODUCT INFORMATION OF TAPENTADOL LIBRA-PHARM FILM-COATED TABLETS AND TAPENTADOL LIBRA-PHARM PROLONGED RELEASE TABLETS WITH THE QRD AND SPC GUIDELINES. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 16950/0136	BUTRANS 5 MICROGRAM/HOUR	GRANTED	PL 16950/0136-0071	PL 16950/0136-0071	22/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO REGISTER UPDATES TO SECTIONS 4.2, 4.3, 4.4 AND 4.8 OF THE SPC TO INCLUDE THE WARNING ¿SKIN REACTION¿, THE CONCEPT OF ¿APPLICATION SITE SKIN REACTIONS¿ AND SPECIFYING A CONTRAINDICATION IN PATIENTS WITH A HISTORY OF APPLICATION SITE REACTIONS AND EMPHASIZING THE NEED TO FOLLOW DIRECTIONS FOR USE TO AVOID POTENTIAL SKIN REACTIONS. 2. TO REGISTER UPDATES TO SECTIONS 4.2, 4.3, 4.4, 4.5, 4.8 AND 5.1 OF THE SPC TO HARMONISE PRODUCT INFORMATION ACROSS ALL OPIOID PRODUCTS IN THE COMPANY AND INCLUDE

										SOME EDITORIAL CHANGES. CONSEQUENTIALLY, THE PIL TEXT HAS BEEN UPDATED.
PL 16950/0137	BUTRANS 10 MICROGRAM/HOUR	GRANTED	PL 16950/0137-0069	PL 16950/0137-0069	22/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO REGISTER UPDATES TO SECTIONS 4.2, 4.3, 4.4 AND 4.8 OF THE SPC TO INCLUDE THE WARNING ¿SKIN REACTION¿, THE CONCEPT OF ¿APPLICATION SITE SKIN REACTIONS¿ AND SPECIFYING A CONTRAINDICATION IN PATIENTS WITH A HISTORY OF APPLICATION SITE REACTIONS AND EMPHASIZING THE NEED TO FOLLOW DIRECTIONS FOR USE TO AVOID POTENTIAL SKIN REACTIONS. 2. TO REGISTER UPDATES TO SECTIONS 4.2, 4.3, 4.4, 4.5, 4.8 AND 5.1 OF THE SPC TO HARMONISE PRODUCT INFORMATION ACROSS ALL OPIOID PRODUCTS IN THE COMPANY AND INCLUDE SOME EDITORIAL CHANGES. CONSEQUENTIALLY, THE

										PIL TEXT HAS BEEN UPDATED.
PL 16950/0138	BUTRANS 20 MICROGRAM/HOUR	GRANTED	PL 16950/0138-0069	PL 16950/0138-0069	22/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO REGISTER UPDATES TO SECTIONS 4.2, 4.3, 4.4 AND 4.8 OF THE SPC TO INCLUDE THE WARNING ¿SKIN REACTION¿, THE CONCEPT OF ¿APPLICATION SITE SKIN REACTIONS¿ AND SPECIFYING A CONTRAINDICATION IN PATIENTS WITH A HISTORY OF APPLICATION SITE REACTIONS AND EMPHASIZING THE NEED TO FOLLOW DIRECTIONS FOR USE TO AVOID POTENTIAL SKIN REACTIONS. 2. TO REGISTER UPDATES TO SECTIONS 4.2, 4.3, 4.4, 4.5, 4.8 AND 5.1 OF THE SPC TO HARMONISE PRODUCT INFORMATION ACROSS ALL OPIOID PRODUCTS IN THE COMPANY AND INCLUDE SOME EDITORIAL CHANGES. CONSEQUENTIALLY, THE PIL TEXT HAS BEEN UPDATED.

PL 16950/0349	BUTRANS 15 MICROGRAM/HOUR	GRANTED	PL 16950/0349-0033	PL 16950/0349-0033	22/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO REGISTER UPDATES TO SECTIONS 4.2, 4.3, 4.4 AND 4.8 OF THE SPC TO INCLUDE THE WARNING ¿SKIN REACTION¿, THE CONCEPT OF ¿APPLICATION SITE SKIN REACTIONS¿ AND SPECIFYING A CONTRAINDICATION IN PATIENTS WITH A HISTORY OF APPLICATION SITE REACTIONS AND EMPHASIZING THE NEED TO FOLLOW DIRECTIONS FOR USE TO AVOID POTENTIAL SKIN REACTIONS. 2. TO REGISTER UPDATES TO SECTIONS 4.2, 4.3, 4.4, 4.5, 4.8 AND 5.1 OF THE SPC TO HARMONISE PRODUCT INFORMATION ACROSS ALL OPIOID PRODUCTS IN THE COMPANY AND INCLUDE SOME EDITORIAL CHANGES. CONSEQUENTIALLY, THE PIL TEXT HAS BEEN UPDATED.
PL 20075/0429	IDARUBICIN 5 MG/5 ML SOLUTION FOR INJECTION	GRANTED	PL 20075/0429-0009	PL 20075/0429-0009	23/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC IN-LINE WITH THE PRODUCT INFORMATION OF

								RD) - CMS		REFERENCE PRODUCT (ZAVEDOS 10 MG POWDER FOR SOLUTION FOR INJECTION WITH PROCEDURE NUMBER: PL 00057/1060 & MAH: PFIZER LIMITED) FOR IDARUBICIN 5MG/5ML, 10MG/10ML & 20MG/20ML SOLUTION FOR INJECTION. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 20075/0525	IDARUBICIN 10 MG/10 ML SOLUTION FOR INJECTION	GRANTED	PL 20075/0525-0010	PL 20075/0525-0010	23/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC IN-LINE WITH THE PRODUCT INFORMATION OF REFERENCE PRODUCT (ZAVEDOS 10 MG POWDER FOR SOLUTION FOR INJECTION WITH PROCEDURE NUMBER: PL 00057/1060 & MAH: PFIZER LIMITED) FOR IDARUBICIN 5MG/5ML, 10MG/10ML & 20MG/20ML SOLUTION FOR INJECTION. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 20075/0526	IDARUBICIN 20 MG/20 ML SOLUTION FOR INJECTION	GRANTED	PL 20075/0526-0009	PL 20075/0526-0009	23/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC IN-LINE WITH THE PRODUCT INFORMATION OF REFERENCE PRODUCT (ZAVEDOS 10 MG POWDER FOR SOLUTION FOR INJECTION WITH PROCEDURE NUMBER: PL

										00057/1060 & MAH: PFIZER LIMITED) FOR IDARUBICIN 5MG/5ML, 10MG/10ML & 20MG/20ML SOLUTION FOR INJECTION. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 16239/0013	NEBILET 5MG TABLETS	GRANTED	PL 16239/0013-0074	PL 16239/0013-0074	24/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6, 4.8 AND 5.3 OF THE SMPC TO ADD A WORDING ON FERTILITY BASED ON NON-CLINICAL STUDIES INCLUDED IN THE CURRENTLY APPROVED DOSSIER AND NEW LITERATURE REFERENCES.
PL 34926/0012	SALVACYL 11.25MG POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 34926/0012-0085	PL 34926/0012-0085	25/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SAFETY SECTIONS OF ALL TRIPTORELIN FORMULATIONS AND ENSURE HARMONISATION AND CONSISTENCY ACROSS ALL TRIPTORELIN FORMULATIONS AND EU COUNTRIES, INCLUDING THE FOLLOWING VARIATIONS: 1. TO REGISTER THE ADDITION OF THE ADVERSE DRUG REACTION (ADR) IN MEN AND WOMEN: ¿PITUITARY APOPLEXY¿ TO THE ADR TABLES IN SECTION 4.8 OF THE SPC. 2. TO REGISTER THE

										HARMONISATION OF THE SPC TO THOSE APPROVED NATIONALLY.
PL 15513/0058	BENYLIN FOUR FLU TABLETS	GRANTED	PL 15513/0058-0086	PL 15513/0058-0086	30/11/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SPC (SECTIONS 4.3, 4.4, 4.8, 4.9*, AND 5.2), AND CONSEQUENTIALLY THE PIL & LABELLING, IN LINE WITH THE CCDS FOR THE COMBINATION OF PARACETAMOL, DIPHENHYDRAMINE HYDROCHLORIDE, AND PSEUDOEPHEDRINE HYDROCHLORIDE. *SPC 4.9 CHANGES INTRODUCED FOLLOWING CLOCK-STOP AT DAY 59.
PL 04416/0948	PREFIBIN 2 MG SUBLINGUAL TABLETS	GRANTED	PL 04416/0948-0023	PL 04416/0948-0023	02/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC AND PIL TO ADOPT TO THE NOT HARMONISED REFERENCE PRODUCT SUBUTEX, SUBLINGUAL TABLETS, INDIVIOR, APRIL 2018. ADDITIONALLY THE SECTION 4 OF THE SMPC HAS BEEN UPDATED ACCORDING TO THE UPDATED EUROPEAN COMMISSION GUIDELINE ON `EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE' (SANTE-2017-11668)

										(9 OCTOBER 2017 EMA/CHMP/302620/2017), THE THRESHOLD FOR SODIUM WITH ORAL USE IS ¿ZERO¿ AND THEREFORE SODIUM HAS TO BE INCLUDED AS EXCIPIENT WITH KNOWN EFFECT.
PL 04416/0949	PREFIBIN 8 MG SUBLINGUAL TABLETS	GRANTED	PL 04416/0949-0023	PL 04416/0949-0023	02/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC AND PIL TO ADOPT TO THE NOT HARMONISED REFERENCE PRODUCT SUBUTEX, SUBLINGUAL TABLETS, INDIVIOR, APRIL 2018. ADDITIONALLY THE SECTION 4 OF THE SMPC HAS BEEN UPDATED ACCORDING TO THE UPDATED EUROPEAN COMMISSION GUIDELINE ON `EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE' (SANTE-2017-11668) (9 OCTOBER 2017 EMA/CHMP/302620/2017), THE THRESHOLD FOR SODIUM WITH ORAL USE IS ¿ZERO¿ AND THEREFORE SODIUM HAS TO BE INCLUDED AS EXCIPIENT WITH KNOWN EFFECT.

PL 00010/0547	MIRENA 20 MICROGRAMS / 24 HOURS INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 00010/0547-0090	PL 00010/0547-0090	03/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2 AND 4.6 OF THE SPC FOLLOWING CONFIRMATION OF A SAFETY SIGNAL. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00010/0547	MIRENA 20 MICROGRAMS / 24 HOURS INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 00010/0547-0093	PL 00010/0547-0093	03/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC WITH RESPECT TO THE NEW DATA ON THE FACTORS ASSOCIATED WITH AN INCREASED RISK OF EXPULSION. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00010/0587	JAYDESS 13.5 MG INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 00010/0587-0050	PL 00010/0587-0050	03/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2 AND 4.6 OF THE SPC FOLLOWING CONFIRMATION OF A SAFETY SIGNAL. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00010/0587	JAYDESS 13.5 MG INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 00010/0587-0056	PL 00010/0587-0056	03/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC WITH RESPECT TO THE NEW DATA ON THE FACTORS ASSOCIATED WITH AN INCREASED RISK OF EXPULSION. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00010/0664	KYLEENA 19.5 MG INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 00010/0664-0030	PL 00010/0664-0030	03/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2 AND 4.6 OF THE SPC FOLLOWING CONFIRMATION OF A SAFETY SIGNAL.

								CMS WORKSHARING		CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00010/0664	KYLEENA 19.5 MG INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 00010/0664-0035	PL 00010/0664-0035	03/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC WITH RESPECT TO THE NEW DATA ON THE FACTORS ASSOCIATED WITH AN INCREASED RISK OF EXPULSION. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0088	TARGOCID 200MG POWDER FOR SOLUTION FOR INJECTION/INFUSION OR ORAL SOLUTION	GRANTED	PL 04425/0088-0110	PL 04425/0088-0110	09/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET (V4) WITH THE SIGNAL ACUTE GENERALIZED EXANTHEMATOUS PUSTULOSIS (AGEP). CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED. LEAFLET MOCK-UP TO BE SUBMITTED AS AN ARTICLE 61(3) NOTIFICATION.
PL 04425/0089	TARGOCID 400MG POWDER FOR SOLUTION FOR INJECTION/INFUSION OR ORAL SOLUTION	GRANTED	PL 04425/0089-0111	PL 04425/0089-0111	09/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET (V4) WITH THE SIGNAL ACUTE GENERALIZED EXANTHEMATOUS PUSTULOSIS (AGEP). CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

										LEAFLET MOCK-UP TO BE SUBMITTED AS AN ARTICLE 61(3) NOTIFICATION.
PL 00289/0584	AZITHROMYCIN 250MG FILM-COATED TABLETS	GRANTED	PL 00289/0584-0058	PL 00289/0584-0058	10/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 2, 3, 4.1, 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.1 AND 6.5 OF THE SPC TO BRING IN LINE WITH REFERENCE PRODUCT- `ZITHROMAX®' AND LATEST QRD TEMPLATE. CONSEQUENTIALLY, THE PIL AND LABEL HAVE BEEN UPDATED.
PL 00289/0585	AZITHROMYCIN 500 MG FILM-COATED TABLETS	GRANTED	PL 00289/0585-0065	PL 00289/0585-0065	10/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 2, 3, 4.1, 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.1 AND 6.5 OF THE SPC TO BRING IN LINE WITH REFERENCE PRODUCT- `ZITHROMAX®' AND LATEST QRD TEMPLATE. CONSEQUENTIALLY, THE PIL AND LABEL HAVE BEEN UPDATED.
PL 20117/0119	BUPRENORPHINE 2MG SUBLINGUAL TABLETS	GRANTED	PL 20117/0119-0039	PL 20117/0119-0039	14/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	DECENTRALISED	TO REGISTER THE INTRODUCTION OF A RISK MANAGEMENT PLAN, VERSION 1.0.

								RD) - CMS RMP		
PL 20117/0119	NATZON 2 MG SUBLINGUAL TABLETS	GRANTED	PL 20117/0119-0039	PL 20117/0119-0039	14/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO REGISTER THE INTRODUCTION OF A RISK MANAGEMENT PLAN, VERSION 1.0.
PL 20117/0120	BUPRENORPHINE 8MG SUBLINGUAL TABLETS	GRANTED	PL 20117/0120-0039	PL 20117/0120-0039	14/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO REGISTER THE INTRODUCTION OF A RISK MANAGEMENT PLAN, VERSION 1.0.
PL 20117/0120	NATZON 8 MG SUBLINGUAL TABLETS	GRANTED	PL 20117/0120-0039	PL 20117/0120-0039	14/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO REGISTER THE INTRODUCTION OF A RISK MANAGEMENT PLAN, VERSION 1.0.
PL 04416/0948	PREFIBIN 2 MG SUBLINGUAL TABLETS	GRANTED	PL 04416/0948-0028	PL 04416/0948-0028	16/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 02, 4.4 AND 4.5 OF THE SMPC AND PIL TO ADD POSSIBLE EFFECTS OF CONCURRENT USE OF BUPRENORPHINE-CONTAINING MEDICINAL PRODUCTS AND GABAPENTINOIDS, SUCH AS PREGABALIN AND GABAPENTIN.
PL 04416/0949	PREFIBIN 8 MG SUBLINGUAL TABLETS	GRANTED	PL 04416/0949-0031	PL 04416/0949-0031	16/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 02, 4.4 AND 4.5 OF THE SMPC AND PIL TO ADD POSSIBLE EFFECTS OF CONCURRENT USE OF BUPRENORPHINE-CONTAINING MEDICINAL

										PRODUCTS AND GABAPENTINOIDS, SUCH AS PREGABALIN AND GABAPENTIN.
PL 17901/0068	NEXIUM 20 MG TABLETS	GRANTED	PL 17901/0068-0179	PL 17901/0068-0179	17/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC TO INCLUDE INFORMATION REGARDING DRUG RASH WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS) FOLLOWING AN INTERNAL SAFETY INFORMATION REVIEW. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 17901/0069	NEXIUM 40MG TABLETS	GRANTED	PL 17901/0069-0170	PL 17901/0069-0170	17/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC TO INCLUDE INFORMATION REGARDING DRUG RASH WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS) FOLLOWING AN INTERNAL SAFETY INFORMATION REVIEW. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 17901/0221	NEXIUM I.V. 40MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 17901/0221-0137	PL 17901/0221-0137	17/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC TO INCLUDE INFORMATION REGARDING DRUG RASH WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS) FOLLOWING AN INTERNAL SAFETY INFORMATION REVIEW. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 17901/0253	NEXIUM 10 MG GASTRO-RESISTANT GRANULES FOR ORAL SUSPENSION, SACHET	GRANTED	PL 17901/0253-0111	PL 17901/0253-0111	17/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC TO INCLUDE INFORMATION REGARDING DRUG RASH WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS) FOLLOWING AN INTERNAL SAFETY INFORMATION REVIEW. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 44124/0008	HEPARIN SODIUM 5 000 I.U./ML, SOLUTION FOR INJECTION	GRANTED	PL 44124/0008-0011	PL 44124/0008-0011	21/12/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5 AND 4.8 OF THE SMPC REGARDING DECREASE OF THE PARTIAL THROMBOPLASTIN TIME WITH SUBSEQUENT REBOUND EFFECT UPON DISCONTINUATION OF NITROGLYCERIN IN HEPARINIZED PATIENTS WAS IDENTIFIED DURING PV REGULATORY MONITORING PERFORMED BY PANPHARMA GROUP, FROM THE FDA WEBSITE. WORDING CORRECTIONS AND ADAPTATION TO QRD TEMPLATE ARE DONE.
PL 08081/0042	FOSRENOL 500MG CHEWABLE TABLETS	GRANTED	PL 08081/0042-0058	PL 08081/0042-0058	13/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 3.0, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2, 6.1 AND 6.5 OF THE SMPC WITH INFORMATION/RESULTS OF PAEDIATRIC CLINICAL STUDY REPORT SPD405-207. ADDITIONALLY SOME

										EDITORIAL CHANGES HAS BEEN MADE TO SMPC.
PL 08081/0043	FOSRENOL 750MG CHEWABLE TABLETS	GRANTED	PL 08081/0043-0059	PL 08081/0043-0059	13/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 3.0, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2, 6.1 AND 6.5 OF THE SMPC WITH INFORMATION/RESULTS OF PAEDIATRIC CLINICAL STUDY REPORT SPD405-207. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC.
PL 08081/0044	FOSRENOL 1000MG CHEWABLE TABLETS	GRANTED	PL 08081/0044-0056	PL 08081/0044-0056	13/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 3.0, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2, 6.1 AND 6.5 OF THE SMPC WITH INFORMATION/RESULTS OF PAEDIATRIC CLINICAL STUDY REPORT SPD405-207. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC.
PL 08081/0057	FOSRENOL 750 MG ORAL POWDER	GRANTED	PL 08081/0057-0033	PL 08081/0057-0033	13/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 3.0, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2, 6.1 AND 6.5 OF THE SMPC WITH INFORMATION/RESULTS OF PAEDIATRIC CLINICAL STUDY REPORT SPD405-207. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC.
PL 08081/0058	FOSRENOL 1000 MG ORAL POWDER	GRANTED	PL 08081/0058-0033	PL 08081/0058-0033	13/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 3.0, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2, 6.1 AND 6.5 OF THE SMPC WITH INFORMATION/RESULTS OF PAEDIATRIC CLINICAL

										STUDY REPORT SPD405-207. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC.
PL 16363/0417	BETAHISTINE 8 MG TABLETS	GRANTED	PL 16363/0417-0024	PL 16363/0417-0024	13/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.6, 4.8, 5.1, 5.2 AND 5.3 OF THE SMPC FRAGMENTS IN LINE WITH THE PRODUCT INFORMATION OF REFERENCE MEDICINAL PRODUCT I.E. BETASERC 8 MG, 16 MG AND 24 MG TABLETS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 16363/0418	BETAHISTINE 16 MG TABLETS	GRANTED	PL 16363/0418-0022	PL 16363/0418-0022	13/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.6, 4.8, 5.1, 5.2 AND 5.3 OF THE SMPC FRAGMENTS IN LINE WITH THE PRODUCT INFORMATION OF REFERENCE MEDICINAL PRODUCT I.E. BETASERC 8 MG, 16 MG AND 24 MG TABLETS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 16363/0419	BETAHISTINE 24 MG TABLETS	GRANTED	PL 16363/0419-0026	PL 16363/0419-0026	13/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.6, 4.8, 5.1, 5.2 AND 5.3 OF THE SMPC FRAGMENTS IN LINE WITH THE PRODUCT INFORMATION OF REFERENCE MEDICINAL PRODUCT I.E. BETASERC 8 MG, 16 MG AND 24 MG

										TABLETS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 30322/0015	HYDROCORTISONE 10 MG TABLETS	GRANTED	PL 30322/0015-0030	PL 30322/0015-0030	13/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.4 OF THE SUMMARY OF PRODUCT CHARACTERISTICS AND PACKAGE LEAFLET TO ADD PHEOCHROMOCYTOMA WARNING. ADDITIONALLY THE RISK MANAGEMENT PLANT (RMP) HAVE BEEN UPDATED FROM VERSION 2.0 TO VERSION 3.0.
PL 16363/0388	ONDANSETRON 4 MG FILM-COATED TABLETS	GRANTED	PL 16363/0388-0022	PL 16363/0388-0022	18/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2 AND 5.3 OF THE SPC TO BRING IN LINE WITH REFERENCE PRODUCT- ZOFRAN 4 MG AND 8 MG TABLETS, LATEST QRD TEMPLATE AND LATEST EXCIPIENT GUIDELINE (EMA/CHMP/302620/2017 REV. 1*- 22 NOVEMBER 2019) REGARDING LACTOSE WARNING. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 16363/0389	ONDANSETRON 8 MG FILM-COATED TABLETS	GRANTED	PL 16363/0389-0022	PL 16363/0389-0022	18/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2 AND 5.3 OF THE SPC TO BRING IN LINE WITH REFERENCE

								RD) - CMS		PRODUCT- ZOFRAN 4 MG AND 8 MG TABLETS, LATEST QRD TEMPLATE AND LATEST EXCIPIENT GUIDELINE (EMA/CHMP/302620/2017 REV. 1*- 22 NOVEMBER 2019) REGARDING LACTOSE WARNING. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 11587/0019	HYDROXYCARBAMIDE MEDAC 500MG CAPSULE, HARD	GRANTED	PL 11587/0019-0051	PL 11587/0019-0051	19/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.6 AND 4.8 OF THE SMPC TO RESOLVE SAFETY-RELEVANT DISCREPANCIES. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET IS UPDATED.
PL 16363/0322	TERBINAFINE 250 MG TABLETS	GRANTED	PL 16363/0322-0029	PL 16363/0322-0029	19/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 AND 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, LAMISIL. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 14427/0026	LEVACT 2.5 MG/ML POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 14427/0026-0056	PL 14427/0026-0056	26/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO UPDATE THE RMP FROM VERSION 7.3 TO VERSION 8.0 TO INCLUDE THE INTERIM REPORT FOR THE BENDAMUSTINE NON‐INTERVENTIONAL POST‐AUTHORISATION SAFETY STUDY (NI‐PASS) (ISN:

										6231‐MA‐3264) WHICH HAS BEEN ESTABLISHED TO ASSESS THE EFFECTIVENESS OF A DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC) AS AN ADDITIONAL RISK MINIMISATION MEASURE AND REMOVE SWEDEN FROM THE STUDY.
PL 01502/0059	MIDAZOLAM 1MG/ML, SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 01502/0059-0059	PL 01502/0059-0059	27/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE MODULE 1.5.2, THE ENVIRONMENTAL RISK ASSESSMENT, PHARMACOVIGILANCE SYSTEM AND RISK MANAGEMENT PLAN, FULFILLING COMMITMENT MADE IN THE REPEAT USE PROCEDURE NL/H/0180/001-003/E/002.
PL 01502/0060	MIDAZOLAM 2MG/ML, SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 01502/0060-0057	PL 01502/0060-0057	27/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE MODULE 1.5.2, THE ENVIRONMENTAL RISK ASSESSMENT, PHARMACOVIGILANCE SYSTEM AND RISK MANAGEMENT PLAN, FULFILLING COMMITMENT MADE IN THE REPEAT USE PROCEDURE NL/H/0180/001-003/E/002.
PL 01502/0061	MIDAZOLAM 5MG/ML, SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 01502/0061-0061	PL 01502/0061-0061	27/01/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE MODULE 1.5.2, THE ENVIRONMENTAL RISK ASSESSMENT, PHARMACOVIGILANCE SYSTEM AND RISK MANAGEMENT PLAN, FULFILLING COMMITMENT MADE IN THE REPEAT USE

										PROCEDURE NL/H/0180/001-003/E/002.
PL 20075/0107	DONEPEZIL HYDROCHLORIDE 5 MG FILM-COATED TABLETS	GRANTED	PL 20075/0107-0038	PL 20075/0107-0038	02/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO INTRODUCE RISK MANAGEMENT PLAN (RMP) FOR DONEPEZIL HYDROCHLORIDE 5 MG / 10 MG FILM-COATED TABLETS.
PL 20075/0108	DONEPEZIL HYDROCHLORIDE 10 MG FILM-COATED TABLETS	GRANTED	PL 20075/0108-0039	PL 20075/0108-0039	02/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO INTRODUCE RISK MANAGEMENT PLAN (RMP) FOR DONEPEZIL HYDROCHLORIDE 5 MG / 10 MG FILM-COATED TABLETS.
PL 04569/0656	ONDANSETRON 2MG/ML SOLUTION FOR INJECTION	GRANTED	PL 04569/0656-0060	PL 04569/0656-0060	03/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8 AND 6.6 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCTS REGISTERED IN IRELAND: ZOFRAN® 4 MG/2 ML (OR 8 MG/4 ML) SOLUTION FOR INJECTION OR INFUSION (LICENCE NUMBERS: PA0896/036/001 AND PA0896/036/002).
PL 11648/0085	GLUCOPHAGE 500MG TABLETS	GRANTED	PL 11648/0085-0053	PL 11648/0085-0053	04/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SMPC IN LINE WITH A REVIEW OF THE FINAL REPORT OF A VOLUNTARY NON-INTERVENTIONAL STUDY EUPAS19686 (CLUE). THE PRODUCT INFORMATION HAS ALSO BEEN ADAPTED TO THE CURRENT QRD TEMPLATE VERSION, AND TO INTRODUCE SOME

										ADDITIONAL EDITORIAL CORRECTIONS. CONSEQUENTIALLY, THE LABEL AND PIL HAVE BEEN UPDATED. THE RISK MANAGEMENT PLAN (RMP) HAS BEEN UPDATED TO VERSION 8.1.
PL 11648/0086	GLUCOPHAGE 850MG TABLETS	GRANTED	PL 11648/0086-0055	PL 11648/0086-0055	04/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SMPC IN LINE WITH A REVIEW OF THE FINAL REPORT OF A VOLUNTARY NON-INTERVENTIONAL STUDY EUPAS19686 (CLUE). THE PRODUCT INFORMATION HAS ALSO BEEN ADAPTED TO THE CURRENT QRD TEMPLATE VERSION, AND TO INTRODUCE SOME ADDITIONAL EDITORIAL CORRECTIONS. CONSEQUENTIALLY, THE LABEL AND PIL HAVE BEEN UPDATED. THE RISK MANAGEMENT PLAN (RMP) HAS BEEN UPDATED TO VERSION 8.1.
PL 50622/0011	CELEBREX 100MG CAPSULES, HARD	GRANTED	PL 50622/0011-0018	PL 50622/0011-0018	09/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE WORDING RELATED TO OLIGOHYDRAMNIOS RISK ASSOCIATED WITH THE USE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID) IN THE SECOND AND THIRD TRIMESTER OF

										PREGNANCY WAS ADDED TO SECTION 4.6 FERTILITY, PREGNANCY AND LACTATION, SUB-SECTION PREGNANCY OF THE CELECOXIB SUMMARY OF PRODUCT CHARACTERISTICS (SMPC) WHERE SUCH INFORMATION WAS MISSING.
PL 50622/0012	CELEBREX 200MG CAPSULES, HARD	GRANTED	PL 50622/0012-0018	PL 50622/0012-0018	09/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE WORDING RELATED TO OLIGOHYDRAMNIOS RISK ASSOCIATED WITH THE USE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID) IN THE SECOND AND THIRD TRIMESTER OF PREGNANCY WAS ADDED TO SECTION 4.6 FERTILITY, PREGNANCY AND LACTATION, SUB-SECTION PREGNANCY OF THE CELECOXIB SUMMARY OF PRODUCT CHARACTERISTICS (SMPC) WHERE SUCH INFORMATION WAS MISSING.
PL 50622/0013	CELECOXIB 100 MG CAPSULES, HARD	GRANTED	PL 50622/0013-0015	PL 50622/0013-0015	09/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE WORDING RELATED TO OLIGOHYDRAMNIOS RISK ASSOCIATED WITH THE USE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID) IN THE SECOND AND THIRD

										TRIMESTER OF PREGNANCY WAS ADDED TO SECTION 4.6 FERTILITY, PREGNANCY AND LACTATION, SUB-SECTION PREGNANCY OF THE CELECOXIB SUMMARY OF PRODUCT CHARACTERISTICS (SMPC) WHERE SUCH INFORMATION WAS MISSING.
PL 50622/0014	CELECOXIB 200 MG CAPSULES, HARD	GRANTED	PL 50622/0014-0015	PL 50622/0014-0015	09/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE WORDING RELATED TO OLIGOHYDRAMNIOS RISK ASSOCIATED WITH THE USE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID) IN THE SECOND AND THIRD TRIMESTER OF PREGNANCY WAS ADDED TO SECTION 4.6 FERTILITY, PREGNANCY AND LACTATION, SUB-SECTION PREGNANCY OF THE CELECOXIB SUMMARY OF PRODUCT CHARACTERISTICS (SMPC) WHERE SUCH INFORMATION WAS MISSING.
PL 50414/0023	ZYDOL SR 50MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0023-0005	PL 50414/0023-0005	11/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC FRAGMENTS FOLLOWING THE RECENT PSUSA OUTCOME OF PSUSA/00003002/202005.

								WORKSHARING		CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0023	ZYDOL SR 50MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50414/0023-0005	PL 50414/0023-0005	11/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC FRAGMENTS FOLLOWING THE RECENT PSUSA OUTCOME OF PSUSA/00003002/202005. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0024	TRAMACET 37.5MG/325MG FILM COATED TABLETS	GRANTED	PL 50414/0024-0007	PL 50414/0024-0007	11/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC FRAGMENTS FOLLOWING THE RECENT PSUSA OUTCOME OF PSUSA/00003002/202005. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0024	TRAMACET 37.5MG/325MG FILM COATED TABLETS	GRANTED	PL 50414/0024-0007	PL 50414/0024-0007	11/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC FRAGMENTS FOLLOWING THE RECENT PSUSA OUTCOME OF PSUSA/00003002/202005. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0024	TRAMADOL HYDROCHLORIDE/PARACETAMOL 37.5MG/325MG FILM-COATED TABLETS	GRANTED	PL 50414/0024-0007	PL 50414/0024-0007	11/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC FRAGMENTS FOLLOWING THE RECENT PSUSA OUTCOME OF PSUSA/00003002/202005. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.

PL 50414/0024	TRAMADOL HYDROCHLORIDE/PARACETAMOL 37.5MG/325MG FILM-COATED TABLETS	GRANTED	PL 50414/0024-0007	PL 50414/0024-0007	11/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC FRAGMENTS FOLLOWING THE RECENT PSUSA OUTCOME OF PSUSA/00003002/202005. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0025	TRAMACET 37.5 MG/325 MG EFFERVESCENT TABLETS	GRANTED	PL 50414/0025-0006	PL 50414/0025-0006	11/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC FRAGMENTS FOLLOWING THE RECENT PSUSA OUTCOME OF PSUSA/00003002/202005. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0025	TRAMACET 37.5 MG/325 MG EFFERVESCENT TABLETS	GRANTED	PL 50414/0025-0006	PL 50414/0025-0006	11/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC FRAGMENTS FOLLOWING THE RECENT PSUSA OUTCOME OF PSUSA/00003002/202005. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 48804/0001	OXYPRO 5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0001-0022	PL 48804/0001-0022	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 48804/0001	OXYPRO 5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0001-0022	PL 48804/0001-0022	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 48804/0002	OXYPRO 10 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0002-0024	PL 48804/0002-0024	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 48804/0002	OXYPRO 10 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0002-0024	PL 48804/0002-0024	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 48804/0003	OXYPRO 15 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0003-0021	PL 48804/0003-0021	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 48804/0003	OXYPRO 15 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0003-0021	PL 48804/0003-0021	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 48804/0004	OXYPRO 20 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0004-0023	PL 48804/0004-0023	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 48804/0004	OXYPRO 20 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0004-0023	PL 48804/0004-0023	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 48804/0005	OXYPRO 30 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0005-0022	PL 48804/0005-0022	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 48804/0005	OXYPRO 30 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0005-0022	PL 48804/0005-0022	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 48804/0006	OXYPRO 40 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0006-0023	PL 48804/0006-0023	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 48804/0006	OXYPRO 40 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0006-0023	PL 48804/0006-0023	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 48804/0007	OXYPRO 60 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0007-0023	PL 48804/0007-0023	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 48804/0007	OXYPRO 60 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0007-0023	PL 48804/0007-0023	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 48804/0008	OXYPRO 80 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0008-0026	PL 48804/0008-0026	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 48804/0008	OXYPRO 80 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 48804/0008-0026	PL 48804/0008-0026	15/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTION 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC BRING IN LINE WITH THE TEXTS OF THE GERMAN REFERENCE PRODUCT-OXYGESIC OF MUNDIPHARMA GMBH. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 04569/0823	DONEPEZIL HYDROCHLORIDE 5MG FILM-COATED TABLETS	GRANTED	PL 04569/0823-0037	PL 04569/0823-0037	16/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 4.4, 4.5, 4.8 AND 6.5 OF THE SMPC DUE TO NEW CLINICAL DATA - INTERNAL SAFETY SIGNAL ON TORSADE DE POINTES/ QT PROLONGATION AND MINOR EXCIPIENTS PI UPDATE AND MINOR EDITORIAL CHANGES. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 04569/0824	DONEPEZIL HYDROCHLORIDE 10MG FILM-COATED TABLETS	GRANTED	PL 04569/0824-0036	PL 04569/0824-0036	16/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 4.4, 4.5, 4.8 AND 6.5 OF THE SMPC DUE TO NEW CLINICAL DATA - INTERNAL SAFETY SIGNAL ON TORSADE DE POINTES/ QT PROLONGATION AND MINOR EXCIPIENTS PI UPDATE AND MINOR EDITORIAL CHANGES. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 15413/0130	HYDROXYCARBAMIDE 500MG HARD CAPSULES	GRANTED	PL 15413/0130-0004	PL 15413/0130-0004	16/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 6.4, 6.5 AND 6.6 OF THE SMPC ACCORDING TO COMMITMENT MADE DURING RUP. CONSEQUENTIALLY, THE LABEL AND PIL HAVE BEEN UPDATED.
PL 25258/0009	MOMETASONE FUROATE 0.1% W/W CREAM	GRANTED	PL 25258/0009-0044	PL 25258/0009-0044	16/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	DECENTRALISED	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO INCLUDE SAFETY INFORMATION RECEIVED

								RD) - CMS		FOR TOPICAL STEROID PRODUCTS FROM MHRA. CONSEQUENTIALLY THE LEAFLET HAS BEEN UPDATED.
PL 16363/0541	ZOPICLONE 3.75 MG FILM-COATED TABLETS	GRANTED	PL 16363/0541-0008	PL 16363/0541-0008	17/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 5.2 AND 5.3 SMPC IN LINE WITH THE REFERENCED PRODUCT ZIMOVANE 3.75 MG & 7.5 MG FILM COATED TABLETS. CONSEQUENTLY THE PIL AND LABEL HAVE BEEN UPDATED.
PL 16363/0542	ZOPICLONE 7.5 MG FILM-COATED TABLETS	GRANTED	PL 16363/0542-0008	PL 16363/0542-0008	17/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 5.2 AND 5.3 SMPC IN LINE WITH THE REFERENCED PRODUCT ZIMOVANE 3.75 MG & 7.5 MG FILM COATED TABLETS. CONSEQUENTLY THE PIL AND LABEL HAVE BEEN UPDATED.
PL 25258/0001	MOMETASONE FUROATE 0.1% W/W OINTMENT	GRANTED	PL 25258/0001-0049	PL 25258/0001-0049	17/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO INCLUDE SAFETY INFORMATION RECEIVED FOR TOPICAL STEROID PRODUCTS FROM MHRA. CONSEQUENTIALLY THE LEAFLET HAS BEEN UPDATED.
PL 20162/0013	DEXAFREE 1 MG/ML, EYE DROPS, SOLUTION	GRANTED	PL 20162/	PL 20162/	18/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE THE RMP TO VERSION 1.0, THE ENVIRONMENTAL RISK

			0013-0038	0013-0038				(STANDARD) - CMS		ASSESSMENT, SUMMARY OF PHARMACOVIGILANCE SYSTEM, QP DECLARATIONS FROM MANUFACTURERS EXCELVISION AND LABORATOIRE UNITHER COUTANCES FOR SANOFI CHIMIE, VERTOLAYE, FRANCE (API MANUFACTURER), THE PIL, LABEL AND OTHER MODULES OF THE DOSSIER IN PREPARATION OF THE SUBMISSION OF A REPEAT-USE PROCEDURE.
PL 00003/0272	LAMICTAL TABLETS 25MG	GRANTED	PL 00003/0272-0152	PL 00003/0272-0152	28/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 5.1 OF THE SPC TO ADD A WARNING CONCERNING CARDIAC SODIUM CHANNEL BLOCKING ACTIVITY OF LAMOTRIGINE AND UPDATE THE PHARMACODYNAMIC INFORMATION BASED ON IN VITRO FINDINGS FROM STUDY 2019N422262_00 THAT INVESTIGATED THE EFFECTS OF LAMOTRIGINE ON WHOLE CELL CURRENT IN HEK293 CELLS STABLY EXPRESSING THE NAV1.5 ION CHANNEL. SMPC SECTIONS 4.9 AND 5.3 HAVE ALSO BEEN

										UPDATED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00003/0273	LAMICTAL TABLETS 50MG	GRANTED	PL 00003/0273-0149	PL 00003/0273-0149	28/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 5.1 OF THE SPC TO ADD A WARNING CONCERNING CARDIAC SODIUM CHANNEL BLOCKING ACTIVITY OF LAMOTRIGINE AND UPDATE THE PHARMACODYNAMIC INFORMATION BASED ON IN VITRO FINDINGS FROM STUDY 2019N422262_00 THAT INVESTIGATED THE EFFECTS OF LAMOTRIGINE ON WHOLE CELL CURRENT IN HEK293 CELLS STABLY EXPRESSING THE NAV1.5 ION CHANNEL. SMPC SECTIONS 4.9 AND 5.3 HAVE ALSO BEEN UPDATED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00003/0274	LAMICTAL TABLETS 100MG	GRANTED	PL 00003/0274-0143	PL 00003/0274-0143	28/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 5.1 OF THE SPC TO ADD A WARNING CONCERNING CARDIAC SODIUM CHANNEL BLOCKING ACTIVITY OF LAMOTRIGINE AND UPDATE THE PHARMACODYNAMIC INFORMATION BASED ON IN VITRO FINDINGS FROM STUDY 2019N422262_00

										THAT INVESTIGATED THE EFFECTS OF LAMOTRIGINE ON WHOLE CELL CURRENT IN HEK293 CELLS STABLY EXPRESSING THE NAV1.5 ION CHANNEL. SMPC SECTIONS 4.9 AND 5.3 HAVE ALSO BEEN UPDATED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00003/0297	LAMICTAL TABLETS 200MG	GRANTED	PL 00003/0297-0149	PL 00003/0297-0149	28/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 5.1 OF THE SPC TO ADD A WARNING CONCERNING CARDIAC SODIUM CHANNEL BLOCKING ACTIVITY OF LAMOTRIGINE AND UPDATE THE PHARMACODYNAMIC INFORMATION BASED ON IN VITRO FINDINGS FROM STUDY 2019N422262_00 THAT INVESTIGATED THE EFFECTS OF LAMOTRIGINE ON WHOLE CELL CURRENT IN HEK293 CELLS STABLY EXPRESSING THE NAV1.5 ION CHANNEL. SMPC SECTIONS 4.9 AND 5.3 HAVE ALSO BEEN UPDATED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00003/0346	LAMICTAL 5 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/	PL 00003/	28/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 5.1 OF THE SPC TO ADD A WARNING

			0346-0162	0346-0162				(STANDARD) - CMS WORKSHARING		CONCERNING CARDIAC SODIUM CHANNEL BLOCKING ACTIVITY OF LAMOTRIGINE AND UPDATE THE PHARMACODYNAMIC INFORMATION BASED ON IN VITRO FINDINGS FROM STUDY 2019N422262_00 THAT INVESTIGATED THE EFFECTS OF LAMOTRIGINE ON WHOLE CELL CURRENT IN HEK293 CELLS STABLY EXPRESSING THE NAV1.5 ION CHANNEL. SMPC SECTIONS 4.9 AND 5.3 HAVE ALSO BEEN UPDATED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00003/0347	LAMICTAL 25 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0347-0159	PL 00003/0347-0159	28/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 5.1 OF THE SPC TO ADD A WARNING CONCERNING CARDIAC SODIUM CHANNEL BLOCKING ACTIVITY OF LAMOTRIGINE AND UPDATE THE PHARMACODYNAMIC INFORMATION BASED ON IN VITRO FINDINGS FROM STUDY 2019N422262_00 THAT INVESTIGATED THE EFFECTS OF LAMOTRIGINE ON WHOLE CELL CURRENT IN HEK293 CELLS STABLY EXPRESSING THE NAV1.5

										ION CHANNEL. SMPC SECTIONS 4.9 AND 5.3 HAVE ALSO BEEN UPDATED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00003/0348	LAMICTAL 100 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0348-0161	PL 00003/0348-0161	28/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 5.1 OF THE SPC TO ADD A WARNING CONCERNING CARDIAC SODIUM CHANNEL BLOCKING ACTIVITY OF LAMOTRIGINE AND UPDATE THE PHARMACODYNAMIC INFORMATION BASED ON IN VITRO FINDINGS FROM STUDY 2019N422262_00 THAT INVESTIGATED THE EFFECTS OF LAMOTRIGINE ON WHOLE CELL CURRENT IN HEK293 CELLS STABLY EXPRESSING THE NAV1.5 ION CHANNEL. SMPC SECTIONS 4.9 AND 5.3 HAVE ALSO BEEN UPDATED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00003/0368	LAMICTAL 50 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0368-0155	PL 00003/0368-0155	28/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 5.1 OF THE SPC TO ADD A WARNING CONCERNING CARDIAC SODIUM CHANNEL BLOCKING ACTIVITY OF LAMOTRIGINE AND UPDATE THE PHARMACODYNAMIC

										INFORMATION BASED ON IN VITRO FINDINGS FROM STUDY 2019N422262_00 THAT INVESTIGATED THE EFFECTS OF LAMOTRIGINE ON WHOLE CELL CURRENT IN HEK293 CELLS STABLY EXPRESSING THE NAV1.5 ION CHANNEL. SMPC SECTIONS 4.9 AND 5.3 HAVE ALSO BEEN UPDATED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00003/0369	LAMICTAL 200 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0369-0153	PL 00003/0369-0153	28/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 5.1 OF THE SPC TO ADD A WARNING CONCERNING CARDIAC SODIUM CHANNEL BLOCKING ACTIVITY OF LAMOTRIGINE AND UPDATE THE PHARMACODYNAMIC INFORMATION BASED ON IN VITRO FINDINGS FROM STUDY 2019N422262_00 THAT INVESTIGATED THE EFFECTS OF LAMOTRIGINE ON WHOLE CELL CURRENT IN HEK293 CELLS STABLY EXPRESSING THE NAV1.5 ION CHANNEL. SMPC SECTIONS 4.9 AND 5.3 HAVE ALSO BEEN UPDATED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 00003/0375	LAMICTAL 2MG CHEWABLE/ DISPERSIBLE/ TABLETS	GRANTED	PL 00003/0375-0131	PL 00003/0375-0131	28/02/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 5.1 OF THE SPC TO ADD A WARNING CONCERNING CARDIAC SODIUM CHANNEL BLOCKING ACTIVITY OF LAMOTRIGINE AND UPDATE THE PHARMACODYNAMIC INFORMATION BASED ON IN VITRO FINDINGS FROM STUDY 2019N422262_00 THAT INVESTIGATED THE EFFECTS OF LAMOTRIGINE ON WHOLE CELL CURRENT IN HEK293 CELLS STABLY EXPRESSING THE NAV1.5 ION CHANNEL. SMPC SECTIONS 4.9 AND 5.3 HAVE ALSO BEEN UPDATED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00289/2293	PALIPERIDONE TEVA 25 MG PROLONGED-RELEASE SUSPENSION FOR INJECTION	GRANTED	PL 00289/2293-0006	PL 00289/2293-0006	01/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMMITMENTS MADE DURING THE PROCEDURE ON 28TH MAY 2021. CONSEQUENTIALLY, THE LABEL AND PIL HAVE BEEN UPDATED.
PL 00289/2294	PALIPERIDONE TEVA 50 MG PROLONGED-RELEASE SUSPENSION FOR INJECTION	GRANTED	PL 00289/2294-0007	PL 00289/2294-0007	01/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMMITMENTS MADE DURING THE PROCEDURE ON 28TH MAY 2021.

										CONSEQUENTIALLY, THE LABEL AND PIL HAVE BEEN UPDATED.
PL 00289/2295	PALIPERIDONE TEVA 75 MG PROLONGED-RELEASE SUSPENSION FOR INJECTION	GRANTED	PL 00289/2295-0007	PL 00289/2295-0007	01/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMMITMENTS MADE DURING THE PROCEDURE ON 28TH MAY 2021. CONSEQUENTIALLY, THE LABEL AND PIL HAVE BEEN UPDATED.
PL 00289/2296	PALIPERIDONE TEVA 100 MG PROLONGED-RELEASE SUSPENSION FOR INJECTION	GRANTED	PL 00289/2296-0007	PL 00289/2296-0007	01/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMMITMENTS MADE DURING THE PROCEDURE ON 28TH MAY 2021. CONSEQUENTIALLY, THE LABEL AND PIL HAVE BEEN UPDATED.
PL 00289/2297	PALIPERIDONE TEVA 150 MG PROLONGED-RELEASE SUSPENSION FOR INJECTION	GRANTED	PL 00289/2297-0007	PL 00289/2297-0007	01/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMMITMENTS MADE DURING THE PROCEDURE ON 28TH MAY 2021. CONSEQUENTIALLY, THE LABEL AND PIL HAVE BEEN UPDATED.
PL 00289/2467	PALIPERIDONE TEVA 150 MG AND PALIPERIDONE TEVA 100 MG PROLONGED-RELEASE SUSPENSION FOR INJECTION	GRANTED	PL 00289/2467-0006	PL 00289/2467-0006	01/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMMITMENTS MADE DURING THE PROCEDURE ON 28TH MAY 2021. CONSEQUENTIALLY, THE LABEL AND PIL HAVE BEEN UPDATED.

PL 00057/0551	PRO-EPANUTIN,CONCENTRATE FOR INFUSION|SOLUTION FOR INJECTION	GRANTED	PL 00057/0551-0094	PL 00057/0551-0094	08/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 4.5 AND 4.8 OF THE SPC IN LINE WITH THE COMPANY'S CORE DATA SHEET (CDS) THAT IS IMPACTING FOSPHENYTOIN. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 20663/0003	BLISSEL 50 MICROGRAMS/G VAGINAL GEL	GRANTED	PL 20663/0003-0019	PL 20663/0003-0019	10/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.6, 4.8, 5.1 AND 5.2 ACCORDING TO THE COMMITMENT SUBMITTED DURING THE RUP (SE/H/0907/001/E/02)
PL 11648/0085	GLUCOPHAGE 500MG TABLETS	GRANTED	PL 11648/0085-0056	PL 11648/0085-0056	12/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE A SAFETY UPDATE OF THE PRODUCT INFORMATION (SMPC SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE AND SECTION 4.8 UNDESIRABLE EFFECTS; PIL SECTION 4 POSSIBLE SIDE EFFECTS) WITH REGARDS TO THE IDENTIFIED RISK OF VITAMIN B12 DEFICIENCY IN ASSOCIATION WITH METFORMIN USE.
PL 11648/0086	GLUCOPHAGE 850MG TABLETS	GRANTED	PL 11648/0086-0058	PL 11648/0086-0058	12/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE A SAFETY UPDATE OF THE PRODUCT INFORMATION (SMPC SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE AND SECTION 4.8 UNDESIRABLE EFFECTS;

										PIL SECTION 4 POSSIBLE SIDE EFFECTS) WITH REGARDS TO THE IDENTIFIED RISK OF VITAMIN B12 DEFICIENCY IN ASSOCIATION WITH METFORMIN USE.
PL 20663/0003	BLISSEL 50 MICROGRAMS/G VAGINAL GEL	GRANTED	PL 20663/0003-0020	PL 20663/0003-0020	16/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE AN ENVIRONMENTAL RISK ASSESSMENT BASED ON LITERATURE DATA.
PL 37071/0008	GABLOFEN 0.05 MG/ML SOLUTION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	GRANTED	PL 37071/0008-0018	PL 37071/0008-0018	25/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.8, 4.9, 5.2 AND 6.6 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, LIORESAL. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 37071/0009	GABLOFEN 0.5 MG/ML SOLUTION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	GRANTED	PL 37071/0009-0019	PL 37071/0009-0019	25/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.8, 4.9, 5.2 AND 6.6 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, LIORESAL. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 37071/0010	GABLOFEN 1 MG/ML SOLUTION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	GRANTED	PL 37071/0010-0018	PL 37071/0010-0018	25/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.8, 4.9, 5.2 AND 6.6 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, LIORESAL. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 37071/0011	GABLOFEN 2 MG/ML SOLUTION FOR INJECTION/INFUSIO	GRANTED	PL 37071/0011-0018	PL 37071/0011-0018	25/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	DECENTRALISED	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.8, 4.9, 5.2 AND 6.6 OF THE SMPC IN LINE WITH THE REFERENCE

	N IN PRE-FILLED SYRINGE							RD) - CMS		PRODUCT, LIORESAL. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 37071/0012	GABLOFEN 0.5 MG/ML SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 37071/0012-0018	PL 37071/0012-0018	25/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.8, 4.9, 5.2 AND 6.6 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, LIORESAL. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 37071/0013	GABLOFEN 1 MG/ML SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 37071/0013-0017	PL 37071/0013-0017	25/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.8, 4.9, 5.2 AND 6.6 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, LIORESAL. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 37071/0014	GABLOFEN 2 MG/ML SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 37071/0014-0017	PL 37071/0014-0017	25/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.8, 4.9, 5.2 AND 6.6 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, LIORESAL. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 11587/0096	ETOPOSIDE 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 11587/0096-0007	PL 11587/0096-0007	29/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4 AND 6 OF THE SPC TO INCLUDE A NEW WARNING REGARDING THE RISK OF SECONDARY MALIGNANCIES AND ADAPTATION ACCORDING TO CURRENT QRD-TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00322/0070	MOVICOL 13.8G SACHET, POWDER	GRANTED	PL 00322/	PL 00322/	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 & 4.5 OF THE SPC, AND CONSEQUENTIALLY THE

	FOR ORAL SOLUTION		0070-0162	0070-0162				(STANDARD) - CMS		PIL, IN LINE WITH NEW PHARMACOVIGILANCE DATA AVAILABLE FOR MOVICOL® RANGE, TO INCLUDE ADVICE THAT THE PRODUCT SHOULD NOT BE USED WITH STARCH-BASED THICKENERS.
PL 00322/0086	MOVICOL CHOCOLATE 13.9G SACHET, POWDER FOR ORAL SOLUTION	GRANTED	PL 00322/0086-0082	PL 00322/0086-0082	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 & 4.5 OF THE SPC, AND CONSEQUENTIALLY THE PIL, IN LINE WITH NEW PHARMACOVIGILANCE DATA AVAILABLE FOR MOVICOL® RANGE, TO INCLUDE ADVICE THAT THE PRODUCT SHOULD NOT BE USED WITH STARCH-BASED THICKENERS.
PL 04569/1061	DONEPEZIL HYDROCHLORIDE 5MG ORODISPERSIBLE TABLETS	GRANTED	PL 04569/1061-0030	PL 04569/1061-0030	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 4.4, 4.5, 4.8 AND 6.5 OF THE SPC IN LINE WITH SIGNAL DETECTION PROCESS COVERING THE PERIOD FROM 01-DEC-2018 TO 30-NOV-2019, `TORSADE DE POINTES/QT INTERVAL PROLONGATION.' ADDITIONALLY, TO IMPLEMENT UPDATES WITH THE LAST APPROVED CMDH ANNOTATED QRD

										TEMPLATE FOR MR/DC PROCEDURES(REF: CMDH /201/2005/REV.10, DATED FEBRUARY 2020) AND UPDATES OF TYPING MISTAKES AND MINOR UPDATES WITHOUT ANY IMPACT ON THE CONTENT OF THE DOSSIER. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED.
PL 04569/1062	DONEPEZIL HYDROCHLORIDE 10MG ORODISPERSIBLE TABLETS	GRANTED	PL 04569/1062-0030	PL 04569/1062-0030	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 4.4, 4.5, 4.8 AND 6.5 OF THE SPC IN LINE WITH SIGNAL DETECTION PROCESS COVERING THE PERIOD FROM 01-DEC-2018 TO 30-NOV-2019, `TORSADE DE POINTES/QT INTERVAL PROLONGATION.' ADDITIONALLY, TO IMPLEMENT UPDATES WITH THE LAST APPROVED CMDH ANNOTATED QRD TEMPLATE FOR MR/DC PROCEDURES(REF: CMDH /201/2005/REV.10, DATED FEBRUARY 2020) AND UPDATES OF TYPING MISTAKES AND MINOR UPDATES WITHOUT ANY IMPACT ON THE CONTENT

										OF THE DOSSIER. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED.
PL 04569/1194	BUPRENORPHINE 0.4 MG SUBLINGUAL TABLETS	GRANTED	PL 04569/1194-0030	PL 04569/1194-0030	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 AND 5.3 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT SUBUTEX, INDIVIOR EUROPE LIMITED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 04569/1195	BUPRENORPHINE 2 MG SUBLINGUAL TABLETS	GRANTED	PL 04569/1195-0031	PL 04569/1195-0031	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 AND 5.3 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT SUBUTEX, INDIVIOR EUROPE LIMITED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 04569/1196	BUPRENORPHINE 8 MG SUBLINGUAL TABLETS	GRANTED	PL 04569/1196-0031	PL 04569/1196-0031	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 AND 5.3 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT SUBUTEX, INDIVIOR EUROPE LIMITED. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 20011/0004	MOVICOL PAEDIATRIC CHOCOLATE FLAVOUR 6.9G SACHET, POWDER FOR ORAL SOLUTION	GRANTED	PL 20011/0004-0104	PL 20011/0004-0104	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 & 4.5 OF THE SPC, AND CONSEQUENTIALLY THE PIL, IN LINE WITH NEW PHARMACOVIGILANCE DATA AVAILABLE FOR MOVICOL® RANGE, TO

										INCLUDE ADVICE THAT THE PRODUCT SHOULD NOT BE USED WITH STARCH-BASED THICKENERS.
PL 20011/0005	MOVICOL PAEDIATRIC PLAIN 6.9G SACHET, POWDER FOR ORAL SOLUTION	GRANTED	PL 20011/0005-0098	PL 20011/0005-0098	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 & 4.5 OF THE SPC, AND CONSEQUENTIALLY THE PIL, IN LINE WITH NEW PHARMACOVIGILANCE DATA AVAILABLE FOR MOVICOL® RANGE, TO INCLUDE ADVICE THAT THE PRODUCT SHOULD NOT BE USED WITH STARCH-BASED THICKENERS.
PL 20011/0007	MOVICOL LIQUID ORANGE FLAVOUR, CONCENTRATE FOR ORAL SOLUTION	GRANTED	PL 20011/0007-0051	PL 20011/0007-0051	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 & 4.5 OF THE SPC, AND CONSEQUENTIALLY THE PIL, IN LINE WITH NEW PHARMACOVIGILANCE DATA AVAILABLE FOR MOVICOL® RANGE, TO INCLUDE ADVICE THAT THE PRODUCT SHOULD NOT BE USED WITH STARCH-BASED THICKENERS.
PL 20011/0037	MOVICOL PLAIN 13.7G SACHET, POWDER FOR ORAL SOLUTION	GRANTED	PL 20011/0037-0020	PL 20011/0037-0020	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 & 4.5 OF THE SPC, AND CONSEQUENTIALLY THE PIL, IN LINE WITH NEW PHARMACOVIGILANCE DATA AVAILABLE FOR MOVICOL® RANGE, TO INCLUDE ADVICE THAT THE PRODUCT SHOULD NOT BE USED WITH

										STARCH-BASED THICKENERS.
PL 20011/0038	MOVICOL READY TO TAKE ORAL SOLUTION IN SACHET	GRANTED	PL 20011/0038-0015	PL 20011/0038-0015	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 & 4.5 OF THE SPC, AND CONSEQUENTIALLY THE PIL, IN LINE WITH NEW PHARMACOVIGILANCE DATA AVAILABLE FOR MOVICOL® RANGE, TO INCLUDE ADVICE THAT THE PRODUCT SHOULD NOT BE USED WITH STARCH-BASED THICKENERS.
PL 50827/0002	SEROQUEL 25 MG FILM-COATED TABLETS	GRANTED	PL 50827/0002-0030	PL 50827/0002-0030	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE 'CONFUSIONAL STATE' UNDER THE NERVOUS SYSTEMS DISORDERS SOC WITH A FREQUENCY OF 'UNCOMMON'. CONSEQUENTIALLY, SECTION 4 OF THE PIL HAS ALSO BEEN UPDATED.
PL 50827/0003	SEROQUEL 100 MG FILM-COATED TABLETS	GRANTED	PL 50827/0003-0028	PL 50827/0003-0028	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE 'CONFUSIONAL STATE' UNDER THE NERVOUS SYSTEMS DISORDERS SOC WITH A FREQUENCY OF 'UNCOMMON'. CONSEQUENTIALLY, SECTION 4 OF THE PIL HAS ALSO BEEN UPDATED.

PL 50827/0004	SEROQUEL 200 MG FILM-COATED TABLETS	GRANTED	PL 50827/0004-0029	PL 50827/0004-0029	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE 'CONFUSIONAL STATE' UNDER THE NERVOUS SYSTEMS DISORDERS SOC WITH A FREQUENCY OF 'UNCOMMON'. CONSEQUENTIALLY, SECTION 4 OF THE PIL HAS ALSO BEEN UPDATED.
PL 50827/0005	SEROQUEL 300 MG FILM-COATED TABLETS	GRANTED	PL 50827/0005-0029	PL 50827/0005-0029	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE 'CONFUSIONAL STATE' UNDER THE NERVOUS SYSTEMS DISORDERS SOC WITH A FREQUENCY OF 'UNCOMMON'. CONSEQUENTIALLY, SECTION 4 OF THE PIL HAS ALSO BEEN UPDATED.
PL 50827/0006	SEROQUEL XL 50 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50827/0006-0040	PL 50827/0006-0040	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE 'CONFUSIONAL STATE' UNDER THE NERVOUS SYSTEMS DISORDERS SOC WITH A FREQUENCY OF 'UNCOMMON'. CONSEQUENTIALLY, SECTION 4 OF THE PIL HAS ALSO BEEN UPDATED.
PL 50827/0007	SEROQUEL XL 150MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50827/0007-0039	PL 50827/0007-0039	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE 'CONFUSIONAL STATE' UNDER THE NERVOUS SYSTEMS DISORDERS SOC WITH A FREQUENCY

								WORKSHARING		OF 'UNCOMMON'. CONSEQUENTIALLY, SECTION 4 OF THE PIL HAS ALSO BEEN UPDATED.
PL 50827/0008	SEROQUEL XL 200 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50827/0008-0039	PL 50827/0008-0039	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE 'CONFUSIONAL STATE' UNDER THE NERVOUS SYSTEMS DISORDERS SOC WITH A FREQUENCY OF 'UNCOMMON'. CONSEQUENTIALLY, SECTION 4 OF THE PIL HAS ALSO BEEN UPDATED.
PL 50827/0009	SEROQUEL XL 300 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50827/0009-0039	PL 50827/0009-0039	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE 'CONFUSIONAL STATE' UNDER THE NERVOUS SYSTEMS DISORDERS SOC WITH A FREQUENCY OF 'UNCOMMON'. CONSEQUENTIALLY, SECTION 4 OF THE PIL HAS ALSO BEEN UPDATED.
PL 50827/0010	SEROQUEL XL 400 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 50827/0010-0039	PL 50827/0010-0039	31/03/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE 'CONFUSIONAL STATE' UNDER THE NERVOUS SYSTEMS DISORDERS SOC WITH A FREQUENCY OF 'UNCOMMON'. CONSEQUENTIALLY, SECTION 4 OF THE PIL HAS ALSO BEEN UPDATED.

PL 10590/0052	ETRIVEX 500 MICROGRAMS/G SHAMPOO	GRANTED	PL 10590/0052-0066	PL 10590/0052-0066	07/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO INTRODUCE RISK MANAGEMENT PLAN (RMP)
PL 10949/0340	ZYBAN 150 MG PROLONGED RELEASE TABLETS	GRANTED	PL 10949/0340-0105	PL 10949/0340-0105	07/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SPC IN LINE WITH THE PRAC RECOMMENDATIONS IN THE SIGNAL ASSESSMENT REPORT ON AGEP (EPITT NO. 19704). CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 37071/0023	SEVOFLURANE 100% INHALATION VAPOUR, LIQUID	GRANTED	PL 37071/0023-0031	PL 37071/0023-0031	08/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6, 5.2 AND 5.3 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT SEVORANE, VLOEISTOF VOOR INHALATIEDAMP BY MAH ABBVIE B.V.
PL 12288/0007	MIBG (I123) INJECTION	GRANTED	PL 12288/0007-0021	PL 12288/0007-0021	12/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE SMPC (SECTIONS 1, 4, 5, 6, 7, 11, 12), AND CONSEQUENTIALLY THE PIL, IN LINE WITH THE EMA GUIDELINE ON CORE SMPC AND PACKAGE LEAFLET FOR RADIOPHARMACEUTICALS, THE LATEST QRD TEMPLATE AND EMA EXCIPIENTS GUIDELINE, WHICH HAVE NO IMPACT ON THE CONTENT OF THE DOSSIER TO HARMONIZE

										THE PRECLINICAL AND CLINICAL SECTIONS OF PRODUCT INFORMATION (PI) OF NATIONALLY APPROVED MEDICINAL PRODUCTS OF THE SAME MAH, BY USING A WORKSHARING PROCEDURE AS RECOMMENDED BY CMDH Q&A SEPT 2019 "LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008".
PL 20011/0006	MOVIPREP ORANGE POWDER FOR ORAL SOLUTION	GRANTED	PL 20011/0006-0072	PL 20011/0006-0072	22/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 & 4.5 OF THE SPC, AND CONSEQUENTIALLY THE PIL, FOLLOWING NEW PHARMACOVIGILANCE DATA ON THE USE OF MOVIPREP & MOVIPREP ORANGE WITH STARCH-BASED FOOD THICKENERS. **IN ORDER TO SUPPORT THE HEALTHCARE PRODUCTS SUPPLY CHAIN AND WIDER RESPONSE TO THE COVID-19 OUTBREAK, TEXT VERSIONS OF THE PILS HAVE BEEN ACCEPTED.**
PL 20011/0039	MOVIPREP POWDER FOR ORAL SOLUTION	GRANTED	PL 20011/	PL 20011/	22/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 & 4.5 OF THE SPC, AND CONSEQUENTIALLY THE

			0039-0030	0039-0030				(STANDARD) - CMS		PIL, FOLLOWING NEW PHARMACOVIGILANCE DATA ON THE USE OF MOVIPREP & MOVIPREP ORANGE WITH STARCH-BASED FOOD THICKENERS. **IN ORDER TO SUPPORT THE HEALTHCARE PRODUCTS SUPPLY CHAIN AND WIDER RESPONSE TO THE COVID-19 OUTBREAK, TEXT VERSIONS OF THE PILS HAVE BEEN ACCEPTED.**
PL 20011/0040	PLENVU POWDER FOR ORAL SOLUTION	GRANTED	PL 20011/0040-0013	PL 20011/0040-0013	22/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.4 & 4.5 OF THE SPC, AND CONSEQUENTIALLY THE PIL, FOLLOWING NEW PHARMACOVIGILANCE DATA ON THE USE OF PLENVU WITH STARCH BASED FOOD THICKENERS. *IN ORDER TO SUPPORT THE HEALTHCARE PRODUCTS SUPPLY CHAIN AND WIDER RESPONSE TO THE COVID-19 OUTBREAK, A TEXT VERSION OF THE PIL HAS BEEN ACCEPTED.*
PL 04569/0978	PIPERACILLIN TAZOBACTAM 2G/0.25G, POWDER	GRANTED	PL 04569/0978-0056	PL 04569/0978-0056	27/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.5, 4.8 AND 5.1 OF THE SPC N LINE WITH THE TEXTS OF THE

	FOR SOLUTION FOR INFUSION							RD) - CMS		REFERENCE MEDICINAL PRODUCT TAZOCIN® FROM PFIZER, APPROVED IN EUROPEAN UNION (PROCEDURE NO. IT/H/0675/001-002, FORMER UK/H/4984/001-002). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04569/0979	PIPERACILLIN TAZOBACTAM 4G/0.5G, POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 04569/0979-0054	PL 04569/0979-0054	27/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.5, 4.8 AND 5.1 OF THE SPC N LINE WITH THE TEXTS OF THE REFERENCE MEDICINAL PRODUCT TAZOCIN® FROM PFIZER, APPROVED IN EUROPEAN UNION (PROCEDURE NO. IT/H/0675/001-002, FORMER UK/H/4984/001-002). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04416/0919	QUETIAPINE 25MG FILM-COATED TABLETS	GRANTED	PL 04416/0919-0065	PL 04416/0919-0065	28/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (VERSION 4.0) TO AMEND THE SUMMARY OF SAFETY CONCERNS TO ALIGN WITH CMDH WEBPAGE SAFETY CONCERNS FOR QUETIAPINE, AND TO ALIGN THE EDUCATIONAL MATERIAL WITH THAT FOR THE REFERENCE PRODUCT.
PL 04416/0962	QUETIAPINE 100 MG FILM-COATED TABLETS	GRANTED	PL 04416/	PL 04416/	28/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE THE RMP (VERSION 4.0) TO AMEND THE SUMMARY OF

			0962-0063	0962-0063				(STANDARD) - CMS WORKSHARING		SAFETY CONCERNS TO ALIGN WITH CMDH WEBPAGE SAFETY CONCERNS FOR QUETIAPINE, AND TO ALIGN THE EDUCATIONAL MATERIAL WITH THAT FOR THE REFERENCE PRODUCT.
PL 04416/0963	QUETIAPINE 150 MG FILM-COATED TABLET	GRANTED	PL 04416/0963-0057	PL 04416/0963-0057	28/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (VERSION 4.0) TO AMEND THE SUMMARY OF SAFETY CONCERNS TO ALIGN WITH CMDH WEBPAGE SAFETY CONCERNS FOR QUETIAPINE, AND TO ALIGN THE EDUCATIONAL MATERIAL WITH THAT FOR THE REFERENCE PRODUCT.
PL 04416/0964	QUETIAPINE 200 MG FILM-COATED TABLET	GRANTED	PL 04416/0964-0060	PL 04416/0964-0060	28/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (VERSION 4.0) TO AMEND THE SUMMARY OF SAFETY CONCERNS TO ALIGN WITH CMDH WEBPAGE SAFETY CONCERNS FOR QUETIAPINE, AND TO ALIGN THE EDUCATIONAL MATERIAL WITH THAT FOR THE REFERENCE PRODUCT.
PL 04416/0965	QUETIAPINE 300 MG FILM-COATED TABLET	GRANTED	PL 04416/0965-0061	PL 04416/0965-0061	28/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP (VERSION 4.0) TO AMEND THE SUMMARY OF SAFETY CONCERNS TO ALIGN WITH CMDH WEBPAGE SAFETY

								WORKSHARING		CONCERNS FOR QUETIAPINE, AND TO ALIGN THE EDUCATIONAL MATERIAL WITH THAT FOR THE REFERENCE PRODUCT.
PL 21039/0009	BETESIL MEDICATED PLASTER 2.25MG	GRANTED	PL 21039/0009-0049	PL 21039/0009-0049	29/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FROM VERSION 1.1 TO 1.2.
PL 29831/0359	OXYCODONE HYDROCHLORIDE 10MG/ML SOLUTION FOR INJECTION OR INFUSION	GRANTED	PL 29831/0359-0031	PL 29831/0359-0031	29/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.2 AND 5.3 OF THE SMPC AND SECTIONS 1, 2, 3 AND 4 OF THE PIL IN LINE WITH THE REFERENCE PRODUCT OXYNORM 10MG/ML INJECTION.
PL 29831/0367	OXYCODONE HYDROCHLORIDE 50 MG/ML SOLUTION FOR INJECTION OR INFUSION	GRANTED	PL 29831/0367-0025	PL 29831/0367-0025	29/04/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.2 AND 5.3 OF THE SMPC AND SECTIONS 1, 2, 3 AND 4 OF THE PIL OF OXYCODONE HYDROCHLORIDE 50 MG/ML SOLUTION FOR INJECTION OR INFUSION IN LINE WITH THE REFERENCE PRODUCT OXYNORM 50 MG/ML SOLUTION FOR INJECTION OR INFUSION BY MAH NAPP PHARMACEUTICALS LTD.
PL 04416/1618	BENZYLPENICILLIN SODIUM 600 MG POWDER FOR	GRANTED	PL 04416/	PL 04416/	03/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.1, 4.2, 4.4, 4.7, 4.8, 5.1 AND 6.6 OF THE SMPC N

	SOLUTION FOR INJECTION / INFUSION		1618-0003	1618-0003				(STANDARD) - CMS		ORDER TO RESPOND TO COMMENTS ON THE TEXTS RAISED DURING THE RUP (FUM008). CONSEQUENTLY, THE PIL AND PACKAGE LABELLING HAVE BEEN UPDATED.
PL 00057/0289	DIFLUCAN 50MG HARD CAPSULES	GRANTED	PL 00057/0289-0150	PL 00057/0289-0150	04/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 6.6 OF THE SMPC AND PIL IN ACCORDANCE WITH ¿QUESTION 3.16 OF THE CMDH Q/A LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 (JULY 2018)¿,
PL 00057/0290	DIFLUCAN 150MG HARD CAPSULES	GRANTED	PL 00057/0290-0129	PL 00057/0290-0129	04/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 6.6 OF THE SMPC AND PIL IN ACCORDANCE WITH ¿QUESTION 3.16 OF THE CMDH Q/A LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 (JULY 2018)¿,
PL 00057/0315	DIFLUCAN 2 MG/ML SOLUTION FOR INFUSION	GRANTED	PL 00057/0315-0117	PL 00057/0315-0117	04/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 6.6 OF THE SMPC AND PIL IN ACCORDANCE WITH ¿QUESTION 3.16 OF THE CMDH Q/A LIST FOR THE SUBMISSION OF VARIATIONS

										ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 (JULY 2018)¿,
PL 00057/0317	DIFLUCAN 200MG HARD CAPSULES	GRANTED	PL 00057/0317-0138	PL 00057/0317-0138	04/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 6.6 OF THE SMPC AND PIL IN ACCORDANCE WITH ¿QUESTION 3.16 OF THE CMDH Q/A LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 (JULY 2018)¿,
PL 00057/0343	DIFLUCAN 10 MG/ML POWDER FOR ORAL SUSPENSION	GRANTED	PL 00057/0343-0122	PL 00057/0343-0122	04/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 6.6 OF THE SMPC AND PIL IN ACCORDANCE WITH ¿QUESTION 3.16 OF THE CMDH Q/A LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 (JULY 2018)¿,
PL 00057/0344	DIFLUCAN 40 MG/ML POWDER FOR ORAL SUSPENSION	GRANTED	PL 00057/0344-0121	PL 00057/0344-0121	04/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 6.6 OF THE SMPC AND PIL IN ACCORDANCE WITH ¿QUESTION 3.16 OF THE CMDH Q/A LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION

										REGULATION (EC) 1234/2008 (JULY 2018)¿,
PL 14895/0313	HUMULIN S 100 IU/ML SOLUTION FOR INJECTION IN VIAL	GRANTED	PL 14895/0313-0020	PL 14895/0313-0020	08/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) ¿ CMS RMP	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO THE RISK MANAGEMENT PLAN FROM VERSION 5.1 TO 6.1. CONSEQUENTIALLY, THE RISK MANAGEMENT PLAN HAS BEEN UPDATED.
PL 14895/0314	HUMULIN S (SOLUBLE) 100 IU/ML SOLUTION FOR INJECTION IN CARTRIDGE	GRANTED	PL 14895/0314-0017	PL 14895/0314-0017	08/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) ¿ CMS RMP	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO THE RISK MANAGEMENT PLAN FROM VERSION 5.1 TO 6.1. CONSEQUENTIALLY, THE RISK MANAGEMENT PLAN HAS BEEN UPDATED.
PL 04595/0006	GYNOXIN 2% VAGINAL CREAM	GRANTED	PL 04595/0006-0028	PL 04595/0006-0028	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6, 4.7, 4.8 AND 4.9 OF THE SMPC AND PIL O HARMONIZE THE SAFETY INFORMATION OF FENTICONAZOLE NITRATE MEDICINAL PRODUCTS FOR GYNAECOLOGICAL USE REGISTERED UNDER BOTH NATIONAL AND DECENTRALIZED PROCEDURES IN EUROPEAN COUNTRIES.
PL 04595/0007	GYNOXIN 200MG VAGINAL CAPSULES	GRANTED	PL 04595/0007-0029	PL 04595/0007-0029	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6, 4.7, 4.8 AND 4.9 OF THE SMPC AND PIL O HARMONIZE THE SAFETY INFORMATION OF FENTICONAZOLE NITRATE MEDICINAL PRODUCTS FOR GYNAECOLOGICAL USE REGISTERED UNDER

										BOTH NATIONAL AND DECENTRALIZED PROCEDURES IN EUROPEAN COUNTRIES.
PL 04595/0008	GYNOXIN 600MG VAGINAL CAPSULES	GRANTED	PL 04595/0008-0031	PL 04595/0008-0031	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6, 4.7, 4.8 AND 4.9 OF THE SMPC AND PIL O HARMONIZE THE SAFETY INFORMATION OF FENTICONAZOLE NITRATE MEDICINAL PRODUCTS FOR GYNAECOLOGICAL USE REGISTERED UNDER BOTH NATIONAL AND DECENTRALIZED PROCEDURES IN EUROPEAN COUNTRIES.
PL 12185/0002	GRANOCYTE 13 MILLION IU/ML POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION IN A PFS	GRANTED	PL 12185/0002-0166	PL 12185/0002-0166	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND SECTION 2 OF THE PIL TO IMPLEMENT THE REVISIONS TO THE TEXT ON SPLENOMEGALY OR SPLENIC RUPTURE AS AGREED IN THE PRAC FINAL ASSESSMENT REPORT ON THE PSUSA OF LENOGRASTIM (PROCEDURE NO. PSUSA/00001839/201910) BUT NOT INCLUDED IN THE CMDH DECISION.
PL 12185/0005	WATER FOR INJECTIONS	GRANTED	PL 12185/0005-0083	PL 12185/0005-0083	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND SECTION 2 OF THE PIL TO IMPLEMENT THE REVISIONS TO THE TEXT ON SPLENOMEGALY OR SPLENIC RUPTURE AS

										AGREED IN THE PRAC FINAL ASSESSMENT REPORT ON THE PSUSA OF LENOGRASTIM (PROCEDURE NO. PSUSA/00001839/201910) BUT NOT INCLUDED IN THE CMDH DECISION.
PL 27925/0015	SANDRENA 0.5MG GEL	GRANTED	PL 27925/0015-0039	PL 27925/0015-0039	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.3-4.5, 4.8 AND 6.6 OF THE SMPC AND PIL OF DIVIGEL 0.1% GEL ACCORDING TO PHARMACOVIGILANCE UPDATE AND LATEST QRD TEMPLATE.
PL 27925/0016	SANDRENA 1MG GEL	GRANTED	PL 27925/0016-0038	PL 27925/0016-0038	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.3-4.5, 4.8 AND 6.6 OF THE SMPC AND PIL OF DIVIGEL 0.1% GEL ACCORDING TO PHARMACOVIGILANCE UPDATE AND LATEST QRD TEMPLATE.
PL 35104/0001	PARACETAMOL 250 MG SUPPOSITORIES	GRANTED	PL 35104/0001-0026	PL 35104/0001-0026	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.1, 4.2, 4.3, 4.6, 4.7, 4.8, 4.9 AND 5.2 OF THE SMPC AND PIL IN-LINE WITH THE QRD FORMAT.
PL 35104/0002	PARACETAMOL 500 MG SUPPOSITORIES	GRANTED	PL 35104/0002-0025	PL 35104/0002-0025	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.1, 4.2, 4.3, 4.6, 4.7, 4.8, 4.9 AND 5.2 OF THE SMPC AND PIL IN-LINE WITH THE QRD FORMAT.
PL 35104/0003	PARACETAMOL 80 MG SUPPOSITORIES	GRANTED	PL 35104/0003-0025	PL 35104/0003-0025	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	DECENTRALISED	TO UPDATE SECTION, 4.1, 4.2, 4.6, 4.7, 4.8, 4.9 AND 5.2 OF THE SMPC FRAGMENTS IN-LINE WITH

								RD) - CMS		THE QRD FORMAT. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 35104/0004	PARACETAMOL 125 MG SUPPOSITORIES	GRANTED	PL 35104/0004-0022	PL 35104/0004-0022	09/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION, 4.1, 4.2, 4.6, 4.7, 4.8, 4.9 AND 5.2 OF THE SMPC FRAGMENTS IN-LINE WITH THE QRD FORMAT. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04425/0658	NOZINAN 25MG TABLETS	GRANTED	PL 04425/0658-0064	PL 04425/0658-0064	10/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6, 4.7 AND 4.8 OF THE SPC RELATED TO THE CCSI AUTHORING PROJECT. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 04425/0659	NOZINAN 25MG/ML SOLUTION FOR INJECTION OR INFUSION	GRANTED	PL 04425/0659-0052	PL 04425/0659-0052	10/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6, 4.7 AND 4.8 OF THE SPC RELATED TO THE CCSI AUTHORING PROJECT. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 04569/1361	MYLAFENT 12 MICROGRAM/HOUR TRANSDERMAL PATCH	GRANTED	PL 04569/1361-0051	PL 04569/1361-0051	10/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE PRODUCT INFORMATION IN LINE WITH THE BRAND LEADER (REFERENCE) PRODUCT: DUROGESIC SMAT TRANSDERMAL PFLASTER, JANSSEN-CILAG REGISTERED VIA NATIONAL PROCEDURE.
PL 04569/1362	MYLAFENT 25 MICROGRAM/HOUR	GRANTED	PL 04569/	PL 04569/	10/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE THE PRODUCT INFORMATION IN LINE WITH THE BRAND

	TRANSDERMAL PATCH		1362-0051	1362-0051				(STANDARD) - CMS		LEADER (REFERENCE) PRODUCT: DUROGESIC SMAT TRANSDERMAL PFLASTER, JANSSEN-CILAG REGISTERED VIA NATIONAL PROCEDURE.
PL 04569/1363	MYLAFENT 50 MICROGRAM/HOUR TRANSDERMAL PATCH	GRANTED	PL 04569/1363-0051	PL 04569/1363-0051	10/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE PRODUCT INFORMATION IN LINE WITH THE BRAND LEADER (REFERENCE) PRODUCT: DUROGESIC SMAT TRANSDERMAL PFLASTER, JANSSEN-CILAG REGISTERED VIA NATIONAL PROCEDURE.
PL 04569/1364	MYLAFENT 75 MICROGRAM/HOUR TRANSDERMAL PATCH	GRANTED	PL 04569/1364-0051	PL 04569/1364-0051	10/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE PRODUCT INFORMATION IN LINE WITH THE BRAND LEADER (REFERENCE) PRODUCT: DUROGESIC SMAT TRANSDERMAL PFLASTER, JANSSEN-CILAG REGISTERED VIA NATIONAL PROCEDURE.
PL 04569/1365	MYLAFENT 100 MICROGRAM/HOUR TRANSDERMAL PATCH	GRANTED	PL 04569/1365-0051	PL 04569/1365-0051	10/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE PRODUCT INFORMATION IN LINE WITH THE BRAND LEADER (REFERENCE) PRODUCT: DUROGESIC SMAT TRANSDERMAL PFLASTER, JANSSEN-CILAG REGISTERED VIA NATIONAL PROCEDURE.
PL 00057/0930	AROMASIN 25MG COATED TABLETS	GRANTED	PL 00057/0930-0030	PL 00057/0930-0030	11/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SMPC AND PIL IN LINE WITH THE MARKETING AUTHORISATION HOLDER'S (MAH) LATEST

								WORKSHARING		CORE DATA SHEET (CDS) VERSION 11.0 DATED 03-JUN-2021 WITH THE BELOW LISTED SCOPE AND CONSEQUENTIALLY REVISIONS TO THE RELEVANT SECTIONS OF THE PIL
PL 00057/1202	EXEMESTANE 25 MG COATED TABLETS	GRANTED	PL 00057/1202-0025	PL 00057/1202-0025	11/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SMPC AND PIL IN LINE WITH THE MARKETING AUTHORISATION HOLDER'S (MAH) LATEST CORE DATA SHEET (CDS) VERSION 11.0 DATED 03-JUN-2021 WITH THE BELOW LISTED SCOPE AND CONSEQUENTIALLY REVISIONS TO THE RELEVANT SECTIONS OF THE PIL
PL 08828/0167	FRESENIUS PROPOVEN 1%, EMULSION FOR INJECTION OR INFUSION	GRANTED	PL 08828/0167-0066	PL 08828/0167-0066	11/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.5 AND 4.8 OF THE SMPC AND LEAFLET FOR THE EU MRP/DCP DE/H/0490/001-002/MR; DE/H/0490/003-004/DC TO THE ORIGINATOR'S TEXTS(DIPRIVAN, ASPEN, IE, DEC 2020):
PL 08828/0168	FRESENIUS PROPOVEN 2%	GRANTED	PL 08828/0168-0053	PL 08828/0168-0053	11/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.5 AND 4.8 OF THE SMPC AND LEAFLET FOR THE EU MRP/DCP DE/H/0490/001-002/MR; DE/H/0490/003-004/DC TO THE ORIGINATOR'S

										TEXTS(DIPRIVAN, ASPEN, IE, DEC 2020):
PL 08828/0239	PROPOVEN 1% EMULSION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	GRANTED	PL 08828/0239-0035	PL 08828/0239-0035	11/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.5 AND 4.8 OF THE SMPC AND LEAFLET FOR THE EU MRP/DCP DE/H/0490/001-002/MR; DE/H/0490/003-004/DC TO THE ORIGINATOR'S TEXTS(DIPRIVAN, ASPEN, IE, DEC 2020):
PL 08828/0240	PROPOVEN 2% EMULSION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	GRANTED	PL 08828/0240-0029	PL 08828/0240-0029	11/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.5 AND 4.8 OF THE SMPC AND LEAFLET FOR THE EU MRP/DCP DE/H/0490/001-002/MR; DE/H/0490/003-004/DC TO THE ORIGINATOR'S TEXTS(DIPRIVAN, ASPEN, IE, DEC 2020):
PL 08828/0144	FRESENIUS PROPOFOL 1%, EMULSION FOR INJECTION OR INFUSION	GRANTED	PL 08828/0144-0099	PL 08828/0144-0099	12/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 4.8 OF THE SMPC AND PIL FOLLOWING ASSESSMENT OF THE SAME CHANGE FOR THE REFERENCE PRODUCT - IMPLEMENTATION OF CHANGE(S) FOR WHICH NO NEW ADDITIONAL DATA IS REQUIRED TO BE SUBMITTED BY THE MAH
PL 08828/0155	PROPOFOL 2% FRESENIUS, EMULSION FOR INJECTION OR INFUSION	GRANTED	PL 08828/0155-0076	PL 08828/0155-0076	12/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 4.8 OF THE SMPC AND PIL FOLLOWING ASSESSMENT OF THE SAME CHANGE FOR THE REFERENCE PRODUCT - IMPLEMENTATION OF

										CHANGE(S) FOR WHICH NO NEW ADDITIONAL DATA IS REQUIRED TO BE SUBMITTED BY THE MAH
PL 16189/0118	REMINYL 4MG/ML ORAL SOLUTION	GRANTED	PL 16189/0118-0006	PL 16189/0118-0006	18/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SMPC AND PIL TO ADD 'EXTRAPYRAMIDAL DISORDER' AS AN ADVERSE DRUG REACTION AS CONSEQUENCE THE SECTION 4.4 OF THE SMPC AND PIL HAS BEEN UPDATED AND I LINE WITH THE QRD TEMPLATE.
PL 16189/0119	REMINYL XL 8 MG PROLONGED-RELEASE CAPSULES	GRANTED	PL 16189/0119-0006	PL 16189/0119-0006	18/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SMPC AND PIL TO ADD 'EXTRAPYRAMIDAL DISORDER' AS AN ADVERSE DRUG REACTION AS CONSEQUENCE THE SECTION 4.4 OF THE SMPC AND PIL HAS BEEN UPDATED AND I LINE WITH THE QRD TEMPLATE.
PL 16189/0120	REMINYL XL 16 MG PROLONGED-RELEASE CAPSULES	GRANTED	PL 16189/0120-0006	PL 16189/0120-0006	18/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SMPC AND PIL TO ADD 'EXTRAPYRAMIDAL DISORDER' AS AN ADVERSE DRUG REACTION AS CONSEQUENCE THE SECTION 4.4 OF THE SMPC AND PIL HAS BEEN UPDATED AND I LINE WITH THE QRD TEMPLATE.

PL 16189/0121	REMINYL XL 24 MG PROLONGED-RELEASE CAPSULES	GRANTED	PL 16189/0121-0006	PL 16189/0121-0006	18/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SMPC AND PIL TO ADD 'EXTRAPYRAMIDAL DISORDER' AS AN ADVERSE DRUG REACTION AS CONSEQUENCE THE SECTION 4.4 OF THE SMPC AND PIL HAS BEEN UPDATED AND I LINE WITH THE QRD TEMPLATE.
PL 41472/0001	ILUVIEN 190 MICROGRAMS INTRAVITREAL IMPLANT IN APPLICATOR	GRANTED	PL 41472/0001-0066	PL 41472/0001-0066	20/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) ¿ CMS RMP	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FOR ILUVIEN HAS BEEN UPDATED TO INCLUDE RESULTS FROM THE COMPLETED POST-AUTHORISATION REGISTRY SAFETY STUDY M-014-12-001 (IRISS) AND THE COMPLETED PHASE III CLINICAL TRIAL PSV-FAI-005 IN CHRONIC NON-INFECTIOUS UVEITIS.
PL 44081/0005	SLYND 4 MG FILM-COATED TABLETS	GRANTED	PL 44081/0005-0002	PL 44081/0005-0002	24/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4 AND 6.1 OF THE SMPC FRAGMENTS FOLLOWING COMMENTS OF THE NEW CMS DURING A REPEAT USE PROCEDURE.
PL 48654/0001	LORAMYC 50MG, MUCO-ADHESIVE BUCCAL TABLETS	GRANTED	PL 48654/0001-0017	PL 48654/0001-0017	24/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1, 4.3, 4.4, 4.5, 4.6 AND 4.8 OF THE SPC TO UPDATE THE SIDE EFFECTS FOLLOWING STUDIES ON NON-MARKEDLY IMMUNOCOMPROMISED

										PATIENTS WITH OROPHARYNGEAL CANDIDIASIS (OPC) (BA 2013/01/07) AND NON-MARKEDLY IMMUNOCOMPROMISED PATIENTS WITH OROPHARYNGEAL CANDIDIASIS (OPC) (SO-1105-02). CONSEQUENTIALLY, THE LABEL AND PIL HAVE BEEN UPDATED.
PL 08265/0031	SEVIKAR HCT 20 MG/5 MG/12.5 MG FILM-COATED TABLETS	GRANTED	PL 08265/0031-0053	PL 08265/0031-0053	26/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL TO ADD THE INTERACTION OF AMLODIPINE WITH MTOR INHIBITING SUBSTANCES WHICH IS ALREADY MENTIONED IN THE SMPC AND PI OF THE AMLODIPINE ORIGINATOR PRODUCTS.
PL 08265/0032	SEVIKAR HCT 40 MG/5 MG/12.5 MG FILM-COATED TABLETS	GRANTED	PL 08265/0032-0051	PL 08265/0032-0051	26/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL TO ADD THE INTERACTION OF AMLODIPINE WITH MTOR INHIBITING SUBSTANCES WHICH IS ALREADY MENTIONED IN THE SMPC AND PI OF THE AMLODIPINE ORIGINATOR PRODUCTS.
PL 08265/0033	SEVIKAR HCT 40 MG/10 MG/12.5 MG FILM-COATED TABLETS	GRANTED	PL 08265/0033-0051	PL 08265/0033-0051	26/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL TO ADD THE INTERACTION OF AMLODIPINE WITH MTOR INHIBITING SUBSTANCES WHICH IS ALREADY

										MENTIONED IN THE SMPC AND PI OF THE AMLODIPINE ORIGINATOR PRODUCTS.
PL 08265/0034	SEVIKAR HCT 40 MG/5 MG/25 MG FILM-COATED TABLETS	GRANTED	PL 08265/0034-0052	PL 08265/0034-0052	26/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL TO ADD THE INTERACTION OF AMLODIPINE WITH MTOR INHIBITING SUBSTANCES WHICH IS ALREADY MENTIONED IN THE SMPC AND PI OF THE AMLODIPINE ORIGINATOR PRODUCTS.
PL 08265/0035	SEVIKAR HCT 40 MG/10 MG/25 MG FILM-COATED TABLETS	GRANTED	PL 08265/0035-0050	PL 08265/0035-0050	26/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL TO ADD THE INTERACTION OF AMLODIPINE WITH MTOR INHIBITING SUBSTANCES WHICH IS ALREADY MENTIONED IN THE SMPC AND PI OF THE AMLODIPINE ORIGINATOR PRODUCTS.
PL 11587/0027	MEDAC DISODIUM PAMIDRONATE 3MG/ML STERILE CONCENTRATE	GRANTED	PL 11587/0027-0036	PL 11587/0027-0036	26/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2, 5.3, 6.3 AND 6.6 OF THE SPC IN LINE WITH REFERENCE PRODUCT AREDIA® (MAH: NOVARTIS). CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 20075/0363	OXYBUTYNIN HYDROCHLORIDE 2.5 MG TABLETS	GRANTED	PL 20075/0363-0027	PL 20075/0363-0027	30/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.3, 4.4, 4.5, 4.8, 4.9, 5.1, 5.2 AND 5.3 OF THE SMPC AND PIL INFORMATION IN LINE WITH THE PRODUCT

								RD) - CMS		INFORMATION OF REFERENCE PRODUCT (DITROPAN 2.5MG, WITH PRODUCT REFERENCE NUMBER: PL 04425/0289; MAH: SANOFI, UNITED KINGDOM AND DITROPAN 5MG, WITH PRODUCT REFERENCE NUMBER: PL 04425/0290; MAH: SANOFI, UNITED KINGDOM).
PL 20075/0364	OXYBUTYNIN HYDROCHLORIDE 5 MG TABLETS	GRANTED	PL 20075/0364-0028	PL 20075/0364-0028	30/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.3, 4.4, 4.5, 4.8, 4.9, 5.1, 5.2 AND 5.3 OF THE SMPC AND PIL INFORMATION IN LINE WITH THE PRODUCT INFORMATION OF REFERENCE PRODUCT (DITROPAN 2.5MG, WITH PRODUCT REFERENCE NUMBER: PL 04425/0289; MAH: SANOFI, UNITED KINGDOM AND DITROPAN 5MG, WITH PRODUCT REFERENCE NUMBER: PL 04425/0290; MAH: SANOFI, UNITED KINGDOM).
PL 00116/0666	MAINTELYTE SOLUTION FOR INFUSION	GRANTED	PL 00116/0666-0012	PL 00116/0666-0012	31/05/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO THE RISK MANAGEMENT PLAN IN LINE WITH CURRENT REQUIREMENTS OF GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICE. THE RISK MANAGEMENT PLAN HAS BEEN UPDATE FROM RMP VERSION 1.1 VERSION DATE: 14 NOV 2017 TO

										RMP VERSION 2.1 VERSION DATE: 21 FEB 2022.
PL 00116/0674	PROPOFOL 10 MG/ML EMULSION FOR INJECTION/INFUSION	GRANTED	PL 00116/0674-0015	PL 00116/0674-0015	09/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 1, 2, 3, 4.1-4.9, 5.1-5.3, 6.2, 6.3, 6.5 AND 6.6 OF THE SMPC AND PIL IN LINE WITH REFERENCE MEDICINAL PRODUCT.
PL 00116/0675	PROPOFOL 20 MG/ML EMULSION FOR INJECTION/INFUSION	GRANTED	PL 00116/0675-0016	PL 00116/0675-0016	09/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 1, 2, 3, 4.1-4.9, 5.1-5.3, 6.2, 6.3, 6.5 AND 6.6 OF THE SMPC AND PIL IN LINE WITH REFERENCE MEDICINAL PRODUCT.
PL 02343/0007	PROGESTERONE 400 MG PESSARIES	GRANTED	PL 02343/0007-0010	PL 02343/0007-0010	09/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO REMOVE THE SIDE EFFECT 'RECTAL NEOPLASM' BASED ON CLINICAL DATA. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 28444/0155	GENHYCO 10 MG TABLETS	GRANTED	PL 28444/0155-0013	PL 28444/0155-0013	10/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE 02, 03, 4.1, 4.2, 4,3, 4,4, 4,5, 4.9, 6.5, AND 6.6 OF THE SMPC, LABELLING, PIL AND RISK MANAGEMENT PLAN AS RESULT OF COMMITMENTS TO THE COMPETENT AUTHORITIES DURING THE REPEAT USE PROCEDURE UK/H/6018/001-002/E/001 SINCE DAY 00, INCLUDING THE REMOVAL OF A THERAPEUTIC INDICATION AND ASSOCIATED INFORMATION.

PL 28444/0155	HYDROCORTISONE 10 MG TABLETS	GRANTED	PL 28444/0155-0013	PL 28444/0155-0013	10/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE 02, 03, 4.1, 4.2, 4,3, 4,4, 4,5, 4.9, 6.5, AND 6.6 OF THE SMPC, LABELLING, PIL AND RISK MANAGEMENT PLAN AS RESULT OF COMMITMENTS TO THE COMPETENT AUTHORITIES DURING THE REPEAT USE PROCEDURE UK/H/6018/001-002/E/001 SINCE DAY 00, INCLUDING THE REMOVAL OF A THERAPEUTIC INDICATION AND ASSOCIATED INFORMATION.
PL 28444/0156	GENHYCO 20 MG TABLETS	GRANTED	PL 28444/0156-0012	PL 28444/0156-0012	10/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE 02, 03, 4.1, 4.2, 4,3, 4,4, 4,5, 4.9, 6.5, AND 6.6 OF THE SMPC, LABELLING, PIL AND RISK MANAGEMENT PLAN AS RESULT OF COMMITMENTS TO THE COMPETENT AUTHORITIES DURING THE REPEAT USE PROCEDURE UK/H/6018/001-002/E/001 SINCE DAY 00, INCLUDING THE REMOVAL OF A THERAPEUTIC INDICATION AND ASSOCIATED INFORMATION.
PL 28444/0156	HYDROCORTISONE 20 MG TABLETS	GRANTED	PL 28444/0156-0012	PL 28444/0156-0012	10/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE 02, 03, 4.1, 4.2, 4,3, 4,4, 4,5, 4.9, 6.5, AND 6.6 OF THE SMPC, LABELLING, PIL AND RISK MANAGEMENT PLAN AS

								RD) - CMS		RESULT OF COMMITMENTS TO THE COMPETENT AUTHORITIES DURING THE REPEAT USE PROCEDURE UK/H/6018/001-002/E/001 SINCE DAY 00, INCLUDING THE REMOVAL OF A THERAPEUTIC INDICATION AND ASSOCIATED INFORMATION.
PL 25215/0026	AMIODARONE HYDROCHLORIDE 50 MG/ML CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 25215/0026-0040	PL 25215/0026-0040	13/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.4 AND 6.6 OF THE SMPC AND PIL ACCORDING TO NEW PHARMACOVIGILANCE DATA RECEIVED AS REPORTS OF CRYSTALLISATION FOR HAMELN AMIODARONE HYDROCHLORDE 50 MG/ML CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION.
PL 34771/0005	PANTOPRAZOLE 40 MG GASTRO-RESISTANT TABLETS	GRANTED	PL 34771/0005-0042	PL 34771/0005-0042	13/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.8, 5.1 AND 5.3 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT ¿PANTOPRAZOLE 40 MG GASTRO-RESISTANT TABLETS, TAKEDA GMBH, GERMANY¿. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.

PL 00289/0455	TEVA LISINOPRIL AND HYDROCHLOROTHIAZIDE 10MG/12.5MG TABLETS	GRANTED	PL 00289/0455-0068	PL 00289/0455-0068	14/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.2 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT ¿ACERCOMP¿ ALONG WITH MINOR EDITORIAL CHANGES AND LATEST QRD TEMPLATE FOR LISINOPRIL / HYDROCHLOROTHIAZIDE 10/12.5MG & 20/12.5MG TABLETS. (DE/H/5952/001-002/MR). CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00289/0456	TEVA LISINOPRIL AND HYDROCHLOROTHIAZIDE 20MG/12.5MG TABLETS	GRANTED	PL 00289/0456-0068	PL 00289/0456-0068	14/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 3, 4.2, 4.3, 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT ¿ACERCOMP¿ ALONG WITH MINOR EDITORIAL CHANGES AND LATEST QRD TEMPLATE FOR LISINOPRIL / HYDROCHLOROTHIAZIDE 10/12.5MG & 20/12.5MG TABLETS. (DE/H/5952/001-002/MR). CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 04569/0604	ZOLPIDEM 10MG FILM COATED TABLETS	GRANTED	PL 04569/0604-0074	PL 04569/0604-0074	14/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND THE PIL IN LINE WITH THE REFERENCE PRODUCT STILNOCT, SANOFI AB WHICH IS NATIONALLY REGISTERED IN SWEDEN. A TYPE II VARIATION

										SUBMISSION HAS BEEN SUBMITTED DUE TO THE REFERENCE PRODUCT NOT BEING HARMONISED ACROSS ALL MEMBER STATES.
PL 21039/0009	BETESIL MEDICATED PLASTER 2.25MG	GRANTED	PL 21039/0009-0050	PL 21039/0009-0050	14/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH A REQUEST RECEIVED FROM THE NATIONAL COMPETENT AUTHORITY MHRA AND REGARDING THE TOPICAL STEROID WITHDRAWAL SYNDROME. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 13761/0008	CIPRALEX 5MG FILM-COATED TABLETS	GRANTED	PL 13761/0008-0115	PL 13761/0008-0115	15/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SPC IN LINE WITH PRAC RECOMMENDATIONS ON THE POTENTIAL RISK OF SEROTONIN SYNDROME AS A RESULT OF A DRUG-DRUG INTERACTION BETWEEN ESCITALOPRAM AND OPIOIDS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 13761/0009	CIPRALEX 10MG FILM-COATED TABLETS	GRANTED	PL 13761/0009-0122	PL 13761/0009-0122	15/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SPC IN LINE WITH PRAC RECOMMENDATIONS ON THE POTENTIAL RISK OF SEROTONIN SYNDROME AS A RESULT OF A DRUG-DRUG INTERACTION BETWEEN ESCITALOPRAM

										AND OPIOIDS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 13761/0011	CIPRALEX 20MG FILM-COATED TABLETS	GRANTED	PL 13761/0011-0117	PL 13761/0011-0117	15/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SPC IN LINE WITH PRAC RECOMMENDATIONS ON THE POTENTIAL RISK OF SEROTONIN SYNDROME AS A RESULT OF A DRUG-DRUG INTERACTION BETWEEN ESCITALOPRAM AND OPIOIDS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 14776/0092	ACTIQ 200 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0092-0054	PL 14776/0092-0054	15/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR EFFENTORA (EU/1/08/441/001-010; EMEA/H/C/000833) AND ACTIQ (DE/H/6124/001-006/MR) FROM VERSION 4.0 TO VERSION 5.1.
PL 14776/0093	ACTIQ 400 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0093-0059	PL 14776/0093-0059	15/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR EFFENTORA (EU/1/08/441/001-010; EMEA/H/C/000833) AND ACTIQ (DE/H/6124/001-006/MR) FROM VERSION 4.0 TO VERSION 5.1.
PL 14776/0094	ACTIQ 600 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0094-0059	PL 14776/0094-0059	15/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR EFFENTORA (EU/1/08/441/001-010; EMEA/H/C/000833) AND ACTIQ (DE/H/6124/001-006/MR) FROM VERSION 4.0 TO VERSION 5.1.

PL 14776/0095	ACTIQ 800 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0095-0063	PL 14776/0095-0063	15/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR EFFENTORA (EU/1/08/441/001-010; EMEA/H/C/000833) AND ACTIQ (DE/H/6124/001-006/MR) FROM VERSION 4.0 TO VERSION 5.1.
PL 14776/0096	ACTIQ 1,200 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0096-0058	PL 14776/0096-0058	15/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR EFFENTORA (EU/1/08/441/001-010; EMEA/H/C/000833) AND ACTIQ (DE/H/6124/001-006/MR) FROM VERSION 4.0 TO VERSION 5.1.
PL 14776/0097	ACTIQ 1,600 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0097-0059	PL 14776/0097-0059	15/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR EFFENTORA (EU/1/08/441/001-010; EMEA/H/C/000833) AND ACTIQ (DE/H/6124/001-006/MR) FROM VERSION 4.0 TO VERSION 5.1.
PL 00057/0989	GENOTROPIN MINIQUICK 0.2MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0989-0056	PL 00057/0989-0056	18/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC AS PART OF THE RECENT ASSESSMENT REPORT OF THE SOMATROPIN PSUR IN THE EU (PROCEDURE NUMBER EMEA/H/C/PSUSA/00002772/202003), THE EMA PRAC RAPPORTEUR REQUESTED THE MAH TO REVISE THE ADR TABLE WITHIN THE SOMATROPIN SMPC. CONSEQUENTLY,

										THE PIL HAS BEEN UPDATED.
PL 00057/0990	GENOTROPIN MINIQUICK 0.4MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0990-0054	PL 00057/0990-0054	18/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC AS PART OF THE RECENT ASSESSMENT REPORT OF THE SOMATROPIN PSUR IN THE EU (PROCEDURE NUMBER EMEA/H/C/PSUSA/00002772/202003), THE EMA PRAC RAPPORTEUR REQUESTED THE MAH TO REVISE THE ADR TABLE WITHIN THE SOMATROPIN SMPC. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00057/0991	GENOTROPIN MINIQUICK 0.6MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0991-0056	PL 00057/0991-0056	18/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC AS PART OF THE RECENT ASSESSMENT REPORT OF THE SOMATROPIN PSUR IN THE EU (PROCEDURE NUMBER EMEA/H/C/PSUSA/00002772/202003), THE EMA PRAC RAPPORTEUR REQUESTED THE MAH TO REVISE THE ADR TABLE WITHIN THE SOMATROPIN SMPC. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00057/0992	GENOTROPIN MINIQUICK 0.8MG POWDER AND SOLVENT FOR	GRANTED	PL 00057/0992-0055	PL 00057/0992-0055	18/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC AS PART OF THE RECENT ASSESSMENT REPORT OF

	SOLUTION FOR INJECTION							RD) - CMS		THE SOMATROPIN PSUR IN THE EU (PROCEDURE NUMBER EMEA/H/C/PSUSA/00002772/202003), THE EMA PRAC RAPPORTEUR REQUESTED THE MAH TO REVISE THE ADR TABLE WITHIN THE SOMATROPIN SMPC. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00057/0993	GENOTROPIN MINIQUICK 1.0MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0993-0055	PL 00057/0993-0055	18/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC AS PART OF THE RECENT ASSESSMENT REPORT OF THE SOMATROPIN PSUR IN THE EU (PROCEDURE NUMBER EMEA/H/C/PSUSA/00002772/202003), THE EMA PRAC RAPPORTEUR REQUESTED THE MAH TO REVISE THE ADR TABLE WITHIN THE SOMATROPIN SMPC. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00057/0994	GENOTROPIN MINIQUICK 1.2MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0994-0055	PL 00057/0994-0055	18/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC AS PART OF THE RECENT ASSESSMENT REPORT OF THE SOMATROPIN PSUR IN THE EU (PROCEDURE NUMBER EMEA/H/C/PSUSA/00002772/202003), THE EMA PRAC RAPPORTEUR REQUESTED THE MAH TO

										REVISE THE ADR TABLE WITHIN THE SOMATROPIN SMPC. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00057/0995	GENOTROPIN MINIQUICK 1.4MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0995-0055	PL 00057/0995-0055	18/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC AS PART OF THE RECENT ASSESSMENT REPORT OF THE SOMATROPIN PSUR IN THE EU (PROCEDURE NUMBER EMEA/H/C/PSUSA/00002772/202003), THE EMA PRAC RAPPORTEUR REQUESTED THE MAH TO REVISE THE ADR TABLE WITHIN THE SOMATROPIN SMPC. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00057/0996	GENOTROPIN MINIQUICK 1.6MG POWDER AND SOVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0996-0054	PL 00057/0996-0054	18/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC AS PART OF THE RECENT ASSESSMENT REPORT OF THE SOMATROPIN PSUR IN THE EU (PROCEDURE NUMBER EMEA/H/C/PSUSA/00002772/202003), THE EMA PRAC RAPPORTEUR REQUESTED THE MAH TO REVISE THE ADR TABLE WITHIN THE SOMATROPIN SMPC. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 00057/0997	GENOTROPIN MINIQUICK 1.8MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0997-0054	PL 00057/0997-0054	18/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC AS PART OF THE RECENT ASSESSMENT REPORT OF THE SOMATROPIN PSUR IN THE EU (PROCEDURE NUMBER EMEA/H/C/PSUSA/00002772/202003), THE EMA PRAC RAPPORTEUR REQUESTED THE MAH TO REVISE THE ADR TABLE WITHIN THE SOMATROPIN SMPC. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00057/0998	GENOTROPIN MINIQUICK 2.0MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0998-0053	PL 00057/0998-0053	18/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC AS PART OF THE RECENT ASSESSMENT REPORT OF THE SOMATROPIN PSUR IN THE EU (PROCEDURE NUMBER EMEA/H/C/PSUSA/00002772/202003), THE EMA PRAC RAPPORTEUR REQUESTED THE MAH TO REVISE THE ADR TABLE WITHIN THE SOMATROPIN SMPC. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 03551/0111	ROCURONIUM 10 MG/ML SOLUTION FOR INJECTION / INFUSION	GRANTED	PL 03551/0111-0039	PL 03551/0111-0039	20/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO REGISTER A NEW RISK MANAGEMENT PLAN (RMP)

PL 46302/0050	TEVETEN 300 MG FILM-COATED TABLETS	GRANTED	PL 46302/0050-0011	PL 46302/0050-0011	20/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4 AND 4.5 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00010/0587	JAYDESS 13.5 MG INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 00010/0587-0057	PL 00010/0587-0057	24/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO REGISTER THE SUBMISSION OF THE 6-MONTHLY INTERIM REPORTS, THE NEXT INTERIM ANALYSES (13TH INTERIM REPORT) OF PASS STUDY- EURAS-LCS12 AS REQUESTED IN THE LAST PSUSA PROCEDURE PSUSA/00001856/201905 AND DESCRIBED IN SECTION 7 OF THE PSUSA ASSESSMENT REPORT AS WELL AS ENDORSED WITH THE CMDH POSITION DATED 30 JAN 2020.
PL 25258/0230	TRAZODONE 150 MG TABLETS	GRANTED	PL 25258/0230-0010	PL 25258/0230-0010	27/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO REGISTER AN UPDATE TO SPC FRAGMENTS 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, AND 5.3 AND THE PIL IN LINE WITH THE OUTCOME OF CMDH PRESS RELEASE - EMA/CMDH/70731/2020 FOR SEROTONERGIC DRUGS AND IN LINE WITH THE REFERENCE PRODUCT. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.

PL 25258/0230	TRAZODONE 150 MG TABLETS	GRANTED	PL 25258/0230-0010	PL 25258/0230-0010	27/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO REGISTER AN UPDATE TO SPC FRAGMENTS 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, AND 5.3 AND THE PIL IN LINE WITH THE OUTCOME OF CMDH PRESS RELEASE - EMA/CMDH/70731/2020 FOR SEROTONERGIC DRUGS AND IN LINE WITH THE REFERENCE PRODUCT. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 25258/0230	TRAZODONE 150 MG TABLETS	GRANTED	PL 25258/0230-0010	PL 25258/0230-0010	27/06/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO REGISTER AN UPDATE TO SPC FRAGMENTS 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, AND 5.3 AND THE PIL IN LINE WITH THE OUTCOME OF CMDH PRESS RELEASE - EMA/CMDH/70731/2020 FOR SEROTONERGIC DRUGS AND IN LINE WITH THE REFERENCE PRODUCT. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50414/0022	VIMOVO 500 MG/20 MG MODIFIED-RELEASE TABLETS	GRANTED	PL 50414/0022-0004	PL 50414/0022-0004	01/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.6 AND 4.8 OF THE SMPC AND PIL REGARDING INCLUDING NEW ADVERSE DRUG REACTIONS TERMS OF ACUTE GENERALIZED EXANTHEMATOUS PUSTULOSIS (AGEP) AND DRUG RASH WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS

										(DRESS) UNDER THE SYSTEM ORGAN CLASS OF `SKIN AND SUBCUTANEOUS TISSUE DISORDERS' WITH FREQUENCY OF `VERY RARE' AND TO INCLUDE A WARNING ON DRESS AS A CLASS EFFECT OF NSAIDS.
PL 06958/0031	AZZALURE, 125 SPEYWOOD UNITS, POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 06958/0031-0094	PL 06958/0031-0094	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 4.7 AND 4.8 OF THE SPC TO ADD THE FOLLOWING ADVERSE DRUG REACTIONS (ADRS) ¿ASTHENIA¿, ¿FATIGUE¿ AND ¿INFLUENZA-LIKE ILLNESS¿. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED. THE MOCK-UP WILL BE SUBMITTED FOR ASSESSMENT VIA AN ARTICLE 61(3) PROCEDURE.
PL 16216/0038	NEUPOGEN SINGLEJECT 30 MU/0.5 ML SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE	GRANTED	PL 16216/0038-0182	PL 16216/0038-0182	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 OF THE SMPC TO ADD A WARNING REGARDING THE ASSOCIATION OBSERVED FOR PEGFILGRASTIM WITH MDS/AML IN BREAST AND LUNG CANCER PATIENTS AND TO RECOMMEND MONITORING OF SUCH PATIENTS FOR MDS/AML. ALSO, TO UPDATE THE RMP, BASED ON UPDATED RESULTS OF

										PEGFILGRASTIM PASS STUDY 20160176. FURTHER, EDITORIAL, QRD, AND EXCIPIENT GUIDELINE UPDATES HAVE BEEN MADE TO THE SPC & PL. 2) TO UPDATE THE SAFETY CONCERNS IN THE RMP FOR NEUPOGEN IN ACCORDANCE WITH THE EMA GUIDELINE ON GVP MODULE V REV 2.
PL 16216/0038	NEUPOGEN SINGLEJECT 30 MU/0.5 ML SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE	GRANTED	PL 16216/0038-0182	PL 16216/0038-0182	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 OF THE SMPC TO ADD A WARNING REGARDING THE ASSOCIATION OBSERVED FOR PEGFILGRASTIM WITH MDS/AML IN BREAST AND LUNG CANCER PATIENTS AND TO RECOMMEND MONITORING OF SUCH PATIENTS FOR MDS/AML. ALSO, TO UPDATE THE RMP, BASED ON UPDATED RESULTS OF PEGFILGRASTIM PASS STUDY 20160176. FURTHER, EDITORIAL, QRD, AND EXCIPIENT GUIDELINE UPDATES HAVE BEEN MADE TO THE SPC & PL.

										2) TO UPDATE THE SAFETY CONCERNS IN THE RMP FOR NEUPOGEN IN ACCORDANCE WITH THE EMA GUIDELINE ON GVP MODULE V REV 2.
PL 16216/0043	NEUPOGEN SINGLEJECT 30 MU/0.5 ML SOLUTION FOR INJECTION	GRANTED	PL 16216/0043-0180	PL 16216/0043-0180	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 OF THE SMPC TO ADD A WARNING REGARDING THE ASSOCIATION OBSERVED FOR PEGFILGRASTIM WITH MDS/AML IN BREAST AND LUNG CANCER PATIENTS AND TO RECOMMEND MONITORING OF SUCH PATIENTS FOR MDS/AML. ALSO, TO UPDATE THE RMP, BASED ON UPDATED RESULTS OF PEGFILGRASTIM PASS STUDY 20160176. FURTHER, EDITORIAL, QRD, AND EXCIPIENT GUIDELINE UPDATES HAVE BEEN MADE TO THE SPC & PL. 2) TO UPDATE THE SAFETY CONCERNS IN THE RMP FOR NEUPOGEN IN ACCORDANCE WITH THE EMA GUIDELINE ON GVP MODULE V REV 2.

PL 16216/0043	NEUPOGEN SINGLEJECT 30 MU/0.5 ML SOLUTION FOR INJECTION	GRANTED	PL 16216/0043-0180	PL 16216/0043-0180	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 OF THE SMPC TO ADD A WARNING REGARDING THE ASSOCIATION OBSERVED FOR PEGFILGRASTIM WITH MDS/AML IN BREAST AND LUNG CANCER PATIENTS AND TO RECOMMEND MONITORING OF SUCH PATIENTS FOR MDS/AML. ALSO, TO UPDATE THE RMP, BASED ON UPDATED RESULTS OF PEGFILGRASTIM PASS STUDY 20160176. FURTHER, EDITORIAL, QRD, AND EXCIPIENT GUIDELINE UPDATES HAVE BEEN MADE TO THE SPC & PL. 2) TO UPDATE THE SAFETY CONCERNS IN THE RMP FOR NEUPOGEN IN ACCORDANCE WITH THE EMA GUIDELINE ON GVP MODULE V REV 2.
PL 16216/0044	NEUPOGEN SINGLEJECT 48 MU/0.5 ML SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE	GRANTED	PL 16216/0044-0178	PL 16216/0044-0178	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 OF THE SMPC TO ADD A WARNING REGARDING THE ASSOCIATION OBSERVED FOR PEGFILGRASTIM WITH MDS/AML IN BREAST AND LUNG CANCER PATIENTS AND TO RECOMMEND

										MONITORING OF SUCH PATIENTS FOR MDS/AML. ALSO, TO UPDATE THE RMP, BASED ON UPDATED RESULTS OF PEGFILGRASTIM PASS STUDY 20160176. FURTHER, EDITORIAL, QRD, AND EXCIPIENT GUIDELINE UPDATES HAVE BEEN MADE TO THE SPC & PL. 2) TO UPDATE THE SAFETY CONCERNS IN THE RMP FOR NEUPOGEN IN ACCORDANCE WITH THE EMA GUIDELINE ON GVP MODULE V REV 2.
PL 16216/0044	NEUPOGEN SINGLEJECT 48 MU/0.5 ML SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE	GRANTED	PL 16216/0044-0178	PL 16216/0044-0178	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 OF THE SMPC TO ADD A WARNING REGARDING THE ASSOCIATION OBSERVED FOR PEGFILGRASTIM WITH MDS/AML IN BREAST AND LUNG CANCER PATIENTS AND TO RECOMMEND MONITORING OF SUCH PATIENTS FOR MDS/AML. ALSO, TO UPDATE THE RMP, BASED ON UPDATED RESULTS OF PEGFILGRASTIM PASS STUDY 20160176. FURTHER, EDITORIAL, QRD, AND EXCIPIENT

										GUIDELINE UPDATES HAVE BEEN MADE TO THE SPC & PL. 2) TO UPDATE THE SAFETY CONCERNS IN THE RMP FOR NEUPOGEN IN ACCORDANCE WITH THE EMA GUIDELINE ON GVP MODULE V REV 2.
PL 45043/0100	LOSEC 10 MG HARD GASTRO-RESISTANT CAPSULES	GRANTED	PL 45043/0100-0011	PL 45043/0100-0011	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO ADD AGEP AND DRESS AS NEW UNDESIRABLE EFFECTS AND CORRECT TYPOGRAPHICAL ERRORS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 45043/0101	LOSEC 20 MG HARD GASTRO-RESISTANT CAPSULES	GRANTED	PL 45043/0101-0010	PL 45043/0101-0010	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO ADD AGEP AND DRESS AS NEW UNDESIRABLE EFFECTS AND CORRECT TYPOGRAPHICAL ERRORS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 45043/0102	LOSEC 40 MG HARD GASTRO-RESISTANT CAPSULES	GRANTED	PL 45043/0102-0010	PL 45043/0102-0010	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO ADD AGEP AND DRESS AS NEW UNDESIRABLE

								RD) - CMS WORKSHARING		EFFECTS AND CORRECT TYPOGRAPHICAL ERRORS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 45043/0103	LOSEC MUPS 10MG GASTRO-RESISTANT TABLETS	GRANTED	PL 45043/0103-0010	PL 45043/0103-0010	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO ADD AGEP AND DRESS AS NEW UNDESIRABLE EFFECTS AND CORRECT TYPOGRAPHICAL ERRORS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 45043/0104	LOSEC MUPS 20MG GASTRO-RESISTANT TABLETS	GRANTED	PL 45043/0104-0009	PL 45043/0104-0009	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO ADD AGEP AND DRESS AS NEW UNDESIRABLE EFFECTS AND CORRECT TYPOGRAPHICAL ERRORS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 45043/0105	LOSEC MUPS 40MG GASTRO-RESISTANT TABLETS	GRANTED	PL 45043/0105-0010	PL 45043/0105-0010	04/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO ADD AGEP AND DRESS AS NEW UNDESIRABLE EFFECTS AND CORRECT TYPOGRAPHICAL ERRORS.

										CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 04569/1577	ENALAPRIL MALEATE AND HYDROCHLOROTHIAZIDE 20 MG/12.5 MG TABLETS	GRANTED	PL 04569/1577-0014	PL 04569/1577-0014	05/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4 AND 4.5 OF THE SMPC DUE TO THE AVAILABILITY OF NEW CLINICAL DATA - INTERNAL SAFETY SIGNAL ON DRUG INTERACTION OF GENERIC ACE INHIBITORS WITH NEPRILYS INHIBITORS. ADDITIONAL MINOR EDITORIAL CHANGES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 20075/0495	TRAZODONE HYDROCHLORIDE 50 MG TABLETS	GRANTED	PL 20075/0495-0012	PL 20075/0495-0012	05/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 4.6 OF THE SMPC IN-LINE WITH REFERENCE PRODUCT (MOLIPAXIN 150 MG TABLETS WITH PROCEDURE REFERENCE NUMBER: PL 17780/0616 & MAH: ZENTIVA PHARMA UK LIMITED) FOR TRAZODONE HYDROCHLORIDE 100 MG TABLETS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 20075/0496	TRAZODONE HYDROCHLORIDE 100 MG TABLETS	GRANTED	PL 20075/0496-0013	PL 20075/0496-0013	05/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 4.6 OF THE SMPC IN-LINE WITH REFERENCE PRODUCT (MOLIPAXIN 150

								RD) - CMS		MG TABLETS WITH PROCEDURE REFERENCE NUMBER: PL 17780/0616 & MAH: ZENTIVA PHARMA UK LIMITED) FOR TRAZODONE HYDROCHLORIDE 100 MG TABLETS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 20075/0497	TRAZODONE HYDROCHLORIDE 150 MG TABLETS	GRANTED	PL 20075/0497-0013	PL 20075/0497-0013	05/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 4.6 OF THE SMPC IN-LINE WITH REFERENCE PRODUCT (MOLIPAXIN 150 MG TABLETS WITH PROCEDURE REFERENCE NUMBER: PL 17780/0616 & MAH: ZENTIVA PHARMA UK LIMITED) FOR TRAZODONE HYDROCHLORIDE 100 MG TABLETS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 27925/0015	SANDRENA 0.5MG GEL	GRANTED	PL 27925/0015-0044	PL 27925/0015-0044	05/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.2, 4.3, 4.4, 4.5, 4.8 AND 6.6 OF THE SMPC TO IMPLEMENTATION OF WORDING AGREED BY THE COMPETENT AUTHORITY. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 27925/0015	SANDRENA 0.5MG GEL	GRANTED	PL 27925/0015-0044	PL 27925/0015-0044	05/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.2, 4.3, 4.4, 4.5, 4.8 AND 6.6 OF THE SMPC TO IMPLEMENTATION OF WORDING AGREED BY THE COMPETENT

								GROUPING		AUTHORITY. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 27925/0016	SANDRENA 1MG GEL	GRANTED	PL 27925/0016-0043	PL 27925/0016-0043	05/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.2, 4.4 AND 4.5 OF THE SMPC TO IMPLEMENTATION OF WORDING AGREED BY THE COMPETENT AUTHORITY. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 27925/0016	SANDRENA 1MG GEL	GRANTED	PL 27925/0016-0043	PL 27925/0016-0043	05/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.2, 4.4 AND 4.5 OF THE SMPC TO IMPLEMENTATION OF WORDING AGREED BY THE COMPETENT AUTHORITY. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 10592/0162	BOOSTRIX SUSPENSION FOR INJECTION IN PFS	GRANTED	PL 10592/0162-0240	PL 10592/0162-0240	11/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 2, 4.3, 4.4, 6.1 OF THE SPC IN LINE WITH HE EUROPEAN ¿GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SEPTEMBER 2009)¿ AND ¿GUIDELINE ON QUALITY ASPECTS INCLUDED IN THE PRODUCT INFORMATION FOR VACCINES FOR HUMAN USE (EMEA/CHMP/BWP/133540/2017)¿. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.

PL 10592/0162	DIPHTHERIA, TETANUS AND PERTUSSIS (ACELLULAR, COMPONENT) VACCINE	GRANTED	PL 10592/0162-0240	PL 10592/0162-0240	11/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 2, 4.3, 4.4, 6.1 OF THE SPC IN LINE WITH HE EUROPEAN ¿GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SEPTEMBER 2009)¿ AND ¿GUIDELINE ON QUALITY ASPECTS INCLUDED IN THE PRODUCT INFORMATION FOR VACCINES FOR HUMAN USE (EMEA/CHMP/BWP/133540/2017)¿. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 10592/0209	DIPHTHERIA, TETANUS, PERTUSSIS AND POLIOMYELITIS (INACTIVATED) VACCINE	GRANTED	PL 10592/0209-0226	PL 10592/0209-0226	11/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 2, 4.4, 6.1 OF THE SPC IN LINE WITH HE EUROPEAN ¿GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SEPTEMBER 2009)¿ AND ¿GUIDELINE ON QUALITY ASPECTS INCLUDED IN THE PRODUCT INFORMATION FOR VACCINES FOR HUMAN USE (EMEA/CHMP/BWP/133540/2017)¿. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.

PL 10592/0209	INFANRIX-IPV, SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 10592/0209-0226	PL 10592/0209-0226	11/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 2, 4.4, 6.1 OF THE SPC IN LINE WITH HE EUROPEAN ¿GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SEPTEMBER 2009)¿ AND ¿GUIDELINE ON QUALITY ASPECTS INCLUDED IN THE PRODUCT INFORMATION FOR VACCINES FOR HUMAN USE (EMEA/CHMP/BWP/133540/2017)¿. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 10592/0214	BOOSTRIX-IPV SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 10592/0214-0290	PL 10592/0214-0290	11/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 2, 4.4, 6.1 OF THE SPC IN LINE WITH HE EUROPEAN ¿GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SEPTEMBER 2009)¿ AND ¿GUIDELINE ON QUALITY ASPECTS INCLUDED IN THE PRODUCT INFORMATION FOR VACCINES FOR HUMAN USE (EMEA/CHMP/BWP/133540/2017)¿. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.

PL 10592/0214	DIPHTHERIA, TETANUS, PERTUSSIS AND POLIOMYELITIS (INACTIVATED) VACCINE	GRANTED	PL 10592/0214-0290	PL 10592/0214-0290	11/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 2, 4.4, 6.1 OF THE SPC IN LINE WITH HE EUROPEAN ¿GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SEPTEMBER 2009)¿ AND ¿GUIDELINE ON QUALITY ASPECTS INCLUDED IN THE PRODUCT INFORMATION FOR VACCINES FOR HUMAN USE (EMEA/CHMP/BWP/133540/2017)¿. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 16189/0034	PANTOPRAZOLE 20 MG GASTRO-RESISTANT TABLETS	GRANTED	PL 16189/0034-0033	PL 16189/0034-0033	12/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO ADD WARNINGS RELATED TO HYPOCALCAEMIA OR HYPOKALAEMIA AND DRESS IN LINE WITH THE CCDS, AND THE EXCIPIENT GUIDELINE AND QRD TEMPLATE. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED. THE CURRENT GRANTED LEAFLET ALREADY INCLUDES THE PROPOSED UPDATES. THEREFORE NO LEAFLET

										HAS BEEN APPROVED WITH THIS SUBMISSION.
PL 16189/0035	PANTOPRAZOLE 40 MG GASTRO-RESISTANT TABLETS	GRANTED	PL 16189/0035-0035	PL 16189/0035-0035	12/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO ADD WARNINGS RELATED TO HYPOCALCAEMIA OR HYPOKALAEMIA AND DRESS IN LINE WITH THE CCDS, AND THE EXCIPIENT GUIDELINE AND QRD TEMPLATE. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED. THE CURRENT GRANTED LEAFLET ALREADY INCLUDES THE PROPOSED UPDATES. THEREFORE NO LEAFLET HAS BEEN APPROVED WITH THIS SUBMISSION.
PL 16189/0036	PROTIUM I.V. 40 MG POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 16189/0036-0035	PL 16189/0036-0035	12/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO ADD WARNINGS RELATED TO HYPOCALCAEMIA OR HYPOKALAEMIA AND DRESS IN LINE WITH THE CCDS, AND THE EXCIPIENT GUIDELINE AND QRD TEMPLATE. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED. THE CURRENT GRANTED

										LEAFLET ALREADY INCLUDES THE PROPOSED UPDATES. THEREFORE NO LEAFLET HAS BEEN APPROVED WITH THIS SUBMISSION.
PL 04500/0015	CYTOTECT CP BIOTEST	GRANTED	PL 04500/0015-0014	PL 04500/0015-0014	14/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO SECTIONS 4.6 OF THE SPC IN LINE WITH THE PRAC PSUR ASSESSMENT REPORT OF THE CYTOTECT CP BIOTEST EU PSUSA PROCEDURE (PSUSA/00000914/202101).
PL 16189/0034	PANTOPRAZOLE 20 MG GASTRO-RESISTANT TABLETS	GRANTED	PL 16189/0034-0039	PL 16189/0034-0039	18/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET UPDATE (CCDS; VERSION 8.0 FOR PANTOPRAZOLE SODIUM; VERSION 6.0 FOR PANTOPRAZOLE MAGNESIUM; DATED 3-DEC-2020). ALSO, TO MAKE A MINOR EDITORIAL AMENDMENT TO THE WORDING IN SECTION 4.4 OF THE SPC IN LINE WITH THE EXCIPIENT GUIDELINE.
PL 16189/0035	PANTOPRAZOLE 40 MG GASTRO-RESISTANT TABLETS	GRANTED	PL 16189/0035-0042	PL 16189/0035-0042	18/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET UPDATE (CCDS; VERSION 8.0 FOR PANTOPRAZOLE SODIUM; VERSION 6.0 FOR PANTOPRAZOLE MAGNESIUM; DATED 3-

										DEC-2020). ALSO, TO MAKE A MINOR EDITORIAL AMENDMENT TO THE WORDING IN SECTION 4.4 OF THE SPC IN LINE WITH THE EXCIPIENT GUIDELINE.
PL 16189/0036	PROTIUM I.V. 40 MG POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 16189/0036-0042	PL 16189/0036-0042	18/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET UPDATE (CCDS; VERSION 8.0 FOR PANTOPRAZOLE SODIUM; VERSION 6.0 FOR PANTOPRAZOLE MAGNESIUM; DATED 3-DEC-2020). ALSO, TO MAKE A MINOR EDITORIAL AMENDMENT TO THE WORDING IN SECTION 4.4 OF THE SPC IN LINE WITH THE EXCIPIENT GUIDELINE.
PL 17780/0744	CINACALCET ZENTIVA 30MG FILM-COATED TABLETS	GRANTED	PL 17780/0744-0022	PL 17780/0744-0022	18/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO THE RISK MANAGEMENT PLAN FROM RMP V1.1 TO RMP V1.2 IN LINE WITH THE REFERENCE PRODUCT. CONSEQUENTIALLY, THE RISK MANAGEMENT PLAN HAS BEEN UPDATED.
PL 17780/0745	CINACALCET ZENTIVA 60MG FILM-COATED TABLETS	GRANTED	PL 17780/0745-0023	PL 17780/0745-0023	18/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO THE RISK MANAGEMENT PLAN FROM RMP V1.1 TO RMP V1.2 IN LINE WITH THE REFERENCE PRODUCT. CONSEQUENTIALLY, THE

										RISK MANAGEMENT PLAN HAS BEEN UPDATED.
PL 17780/0746	CINACALCET ZENTIVA 90MG FILM-COATED TABLETS	GRANTED	PL 17780/0746-0025	PL 17780/0746-0025	18/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO REGISTER AN UPDATE TO THE RISK MANAGEMENT PLAN FROM RMP V1.1 TO RMP V1.2 IN LINE WITH THE REFERENCE PRODUCT. CONSEQUENTIALLY, THE RISK MANAGEMENT PLAN HAS BEEN UPDATED.
PL 31654/0008	PROMIXIN, 1 MILLION INTERNATIONAL UNITS (IU) POWDER FOR NEBULISER SOLUTION.	GRANTED	PL 31654/0008-0016	PL 31654/0008-0016	21/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SMPC AND PIL IN LINE WITH THE COMPANY CORE SAFETY SHEET OF THE PRODUCT) CCDS AS FOLLOW: 1) TO UPDATE SECTION 4.8 OF THE SMPC FOR ADDING A NEW DRUG ADVERSE EVENT, CHOKING SENSATION. 2) TO UPDATE SECTION 5.3 OF THE SMPC WITH THE OUTCOMES OF NON-CLINICAL STUDIES AND AVAILABLE LITERATURE REFERENCES. AS A CONSEQUENCE OF THE 5.3 SECTION UPDATE THE SECTION 4.6 HAS BEEN UPDATED UNDER THE SAME SCOPE. CONSEQUENTIALLY THE PATIENT INFORMATION LEAFLET HAS BEEN UPDATED.

PL 50622/0018	EFEXOR XL 150MG CAPSULES	GRANTED	PL 50622/0018-0014	PL 50622/0018-0014	25/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SPC TO ADD ¿OPIOIDS (E.G...)¿ PRIOR TO THE LIST OF OPIOIDS ALREADY MENTIONED UNDER THE SUBHEADING ¿SEROTONIN SYNDROME¿ TO CLARIFY THAT THE WARNING IS RELATED TO OPIOIDS AS A CLASS, BRINGING IN LINE WITH THE CCDS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 50622/0019	EFEXOR XL 225 MG HARD PROLONGED-RELEASE CAPSULES	GRANTED	PL 50622/0019-0011	PL 50622/0019-0011	25/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SPC TO ADD ¿OPIOIDS (E.G...)¿ PRIOR TO THE LIST OF OPIOIDS ALREADY MENTIONED UNDER THE SUBHEADING ¿SEROTONIN SYNDROME¿ TO CLARIFY THAT THE WARNING IS RELATED TO OPIOIDS AS A CLASS, BRINGING IN LINE WITH THE CCDS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 50622/0020	EFEXOR XL 75MG CAPSULES	GRANTED	PL 50622/0020-0012	PL 50622/0020-0012	25/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SPC TO ADD ¿OPIOIDS (E.G...)¿ PRIOR TO THE LIST OF OPIOIDS ALREADY

								CMS WORKSHARING		MENTIONED UNDER THE SUBHEADING ¿SEROTONIN SYNDROME¿ TO CLARIFY THAT THE WARNING IS RELATED TO OPIOIDS AS A CLASS, BRINGING IN LINE WITH THE CCDS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 16363/0319	BISOPROLOL FUMARATE 5 MG FILM-COATED TABLETS	GRANTED	PL 16363/0319-0037	PL 16363/0319-0037	26/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO UPDATE SECTIONS 4.2-4.5, 4.8, 4.9 AND 5.1-5.3 OF THE SMPC AND PIL TO BRING THE PRODUCT INFORMATION OF BISOPROLOL 5 MG & 10 MG FILM-COATED TABLETS IN LINE WITH THE PRODUCT INFORMATION OF REFERENCE MEDICINAL PRODUCT THE RMP HAS ALSO BEEN UPDATED
PL 16363/0320	BISOPROLOL FUMARATE 10 MG FILM-COATED TABLETS	GRANTED	PL 16363/0320-0037	PL 16363/0320-0037	26/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	DECENTRALISED	TO UPDATE SECTIONS 4.2-4.5, 4.8, 4.9 AND 5.1-5.3 OF THE SMPC AND PIL TO BRING THE PRODUCT INFORMATION OF BISOPROLOL 5 MG & 10 MG FILM-COATED TABLETS IN LINE WITH THE PRODUCT INFORMATION OF

										REFERENCE MEDICINAL PRODUCT THE RMP HAS ALSO BEEN UPDATED
PL 00289/0783	CO-CARELDOPA TABLETS 10/100	GRANTED	PL 00289/0783-0053	PL 00289/0783-0053	27/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.7, 4.8, 5.1 AND 5.3 OF THE SPC N-LINE WITH THE REFERENCE PRODUCT ¿SINEMET¿. CONSEQUENTIALLY, THE LABEL AND LEAFLET HAS BEEN UPDATED.
PL 00289/0784	CO-CARELDOPA TABLETS 25/100	GRANTED	PL 00289/0784-0064	PL 00289/0784-0064	27/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.7, 4.8, 5.1 AND 5.3 OF THE SPC N-LINE WITH THE REFERENCE PRODUCT ¿SINEMET¿. CONSEQUENTIALLY, THE LABEL AND LEAFLET HAS BEEN UPDATED.
PL 00289/0785	CO-CARELDOPA TABLETS 25/250	GRANTED	PL 00289/0785-0068	PL 00289/0785-0068	27/07/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.7, 4.8, 5.1 AND 5.3 OF THE SPC N-LINE WITH THE REFERENCE PRODUCT ¿SINEMET¿. CONSEQUENTIALLY, THE LABEL AND LEAFLET HAS BEEN UPDATED.
PL 18380/0001	MONOFER 100 MG/ML SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 18380/0001-0058	PL 18380/0001-0058	01/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS GROUPING	MUTUAL RECOGNITION	1.C.I.3.B: TO UPDATE SECTION 4.6 AND 5.1 OF THE SMPC AND SECTION 2 OF THE PIL WITH DATA ON COMPLETED STUDIES, IBD-03 AND PREG-01. 2. C.I.11.A: DELETION OF

										PASS CONDITION 3. C.I.12:TO UPDATE SMPC AND PIL WITH REMOVAL OF BLACK WARNING TRIANGLE AND THE RELATED STATEMENT. AS A CONSEQUENCE OF THE ABOVE VARIATIONS THE RMP HAS BEEN UPDATED FROM VERSION 7.0 TO VERSION 9.0, REFLECTING THE NEWCLINICAL STUDIES AND THE COMPLETED FOLLOW-UP ON REFERRAL EMEA/H/A-31/1322.
PL 18380/0001	MONOFER 100 MG/ML SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 18380/0001-0058	PL 18380/0001-0058	01/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS GROUPING	MUTUAL RECOGNITION	1.C.I.3.B: TO UPDATE SECTION 4.6 AND 5.1 OF THE SMPC AND SECTION 2 OF THE PIL WITH DATA ON COMPLETED STUDIES, IBD-03 AND PREG-01. 2. C.I.11.A: DELETION OF PASS CONDITION 3. C.I.12:TO UPDATE SMPC AND PIL WITH REMOVAL OF BLACK WARNING TRIANGLE AND THE RELATED STATEMENT. AS A CONSEQUENCE OF THE ABOVE VARIATIONS THE RMP HAS BEEN UPDATED FROM VERSION

										7.0 TO VERSION 9.0, REFLECTING THE NEWCLINICAL STUDIES AND THE COMPLETED FOLLOW-UP ON REFERRAL EMEA/H/A-31/1322.
PL 18380/0001	MONOFER 100 MG/ML SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 18380/0001-0058	PL 18380/0001-0058	01/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS GROUPING	MUTUAL RECOGNITION	1.C.I.3.B: TO UPDATE SECTION 4.6 AND 5.1 OF THE SMPC AND SECTION 2 OF THE PIL WITH DATA ON COMPLETED STUDIES, IBD-03 AND PREG-01. 2. C.I.11.A: DELETION OF PASS CONDITION 3. C.I.12:TO UPDATE SMPC AND PIL WITH REMOVAL OF BLACK WARNING TRIANGLE AND THE RELATED STATEMENT. AS A CONSEQUENCE OF THE ABOVE VARIATIONS THE RMP HAS BEEN UPDATED FROM VERSION 7.0 TO VERSION 9.0, REFLECTING THE NEWCLINICAL STUDIES AND THE COMPLETED FOLLOW-UP ON REFERRAL EMEA/H/A-31/1322.
PL 13761/0028	CIPRALEX 20 MG/ML ORAL DROPS, SOLUTION	GRANTED	PL 13761/0028-0069	PL 13761/0028-0069	02/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	DECENTRALISED	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SPC IN LINE WITH PRAC RECOMMENDATIONS ON THE POTENTIAL RISK OF

								RD) - CMS		SEROTONIN SYNDROME AS A RESULT OF A DRUG-DRUG INTERACTION BETWEEN ESCITALOPRAM AND OPIOIDS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 03551/0055	PROPOFOL-LIPURO 1% (10 MG/ML)	GRANTED	PL 03551/0055-0071	PL 03551/0055-0071	19/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4 OF THE SMPC TO INCLUDE NE WARNING CONCERNING DOSE REDUCTION IN PATIENTS WITH HYPOPROTEINAEMIA. 2) TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE NEW UNDESIRABLE EFFECTS 3) TO UPDATE SECTION 4.2 OF THE SMPC WITH ¿METHOD AND DURATION OF ADMINISTRATION¿ ADAPTING THE USE OF THE SYRINGE PUMP FOR SMALL VOLUMES ONLY. 4) TO UPDATE THE PRODUCT INFORMATION TEXT AND PIL IN LINE WITH THE ORIGINATOR FOR PROPOFOL 1% AND 2% IS DISOPRIVAN 1% BY ZENECA AND FOR ROPOFOL 0.5 % IS DISOPRIVAN 1%, EMULSION FOR INJECTION OR INFUSION BY ZENECA.

										ADDITIONALLY THE PRODUCT INFORMATION HAVE BEEN UPDATED IN IN LINE WITH EXCIPIENT GUIDELINE AND QRD TEMPLATE.
PL 03551/0055	PROPOFOL-LIPURO 1% (10 MG/ML)	GRANTED	PL 03551/0055-0071	PL 03551/0055-0071	19/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4 OF THE SMPC TO INCLUDE NE WARNING CONCERNING DOSE REDUCTION IN PATIENTS WITH HYPOPROTEINAEMIA. 2) TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE NEW UNDESIRABLE EFFECTS 3) TO UPDATE SECTION 4.2 OF THE SMPC WITH ¿METHOD AND DURATION OF ADMINISTRATION¿ ADAPTING THE USE OF THE SYRINGE PUMP FOR SMALL VOLUMES ONLY. 4) TO UPDATE THE PRODUCT INFORMATION TEXT AND PIL IN LINE WITH THE ORIGINATOR FOR PROPOFOL 1% AND 2% IS DISOPRIVAN 1% BY ZENECA AND FOR ROPOFOL 0.5 % IS DISOPRIVAN 1%, EMULSION FOR INJECTION OR INFUSION BY ZENECA. ADDITIONALLY THE

										PRODUCT INFORMATION HAVE BEEN UPDATED IN IN LINE WITH EXCIPIENT GUIDELINE AND QRD TEMPLATE.
PL 03551/0066	PROPOFOL-LIPURO 2 % (20 MG/ML) EMULSION FOR INJECTION OR INFUSION	GRANTED	PL 03551/0066-0054	PL 03551/0066-0054	19/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4 OF THE SMPC TO INCLUDE NE WARNING CONCERNING DOSE REDUCTION IN PATIENTS WITH HYPOPROTEINAEMIA. 2) TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE NEW UNDESIRABLE EFFECTS 3) TO UPDATE SECTION 4.2 OF THE SMPC WITH ¿METHOD AND DURATION OF ADMINISTRATION¿ ADAPTING THE USE OF THE SYRINGE PUMP FOR SMALL VOLUMES ONLY. 4) TO UPDATE THE PRODUCT INFORMATION TEXT AND PIL IN LINE WITH THE ORIGINATOR FOR PROPOFOL 1% AND 2% IS DISOPRIVAN 1% BY ZENECA AND FOR ROPOFOL 0.5 % IS DISOPRIVAN 1%, EMULSION FOR INJECTION OR INFUSION BY ZENECA. ADDITIONALLY THE PRODUCT INFORMATION

										HAVE BEEN UPDATED IN IN LINE WITH EXCIPIENT GUIDELINE AND QRD TEMPLATE.
PL 03551/0066	PROPOFOL-LIPURO 2 % (20 MG/ML) EMULSION FOR INJECTION OR INFUSION	GRANTED	PL 03551/0066-0054	PL 03551/0066-0054	19/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4 OF THE SMPC TO INCLUDE NE WARNING CONCERNING DOSE REDUCTION IN PATIENTS WITH HYPOPROTEINAEMIA. 2) TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE NEW UNDESIRABLE EFFECTS 3) TO UPDATE SECTION 4.2 OF THE SMPC WITH ¿METHOD AND DURATION OF ADMINISTRATION¿ ADAPTING THE USE OF THE SYRINGE PUMP FOR SMALL VOLUMES ONLY. 4) TO UPDATE THE PRODUCT INFORMATION TEXT AND PIL IN LINE WITH THE ORIGINATOR FOR PROPOFOL 1% AND 2% IS DISOPRIVAN 1% BY ZENECA AND FOR ROPOFOL 0.5 % IS DISOPRIVAN 1%, EMULSION FOR INJECTION OR INFUSION BY ZENECA. ADDITIONALLY THE PRODUCT INFORMATION HAVE BEEN UPDATED IN

										IN LINE WITH EXCIPIENT GUIDELINE AND QRD TEMPLATE.
PL 03551/0113	PROPOFOL-LIPURO 0.5% (5MG/ML) EMULSION FOR INJECTION OR INFUSION	GRANTED	PL 03551/0113-0033	PL 03551/0113-0033	19/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4 OF THE SMPC TO INCLUDE NE WARNING CONCERNING DOSE REDUCTION IN PATIENTS WITH HYPOPROTEINAEMIA. 2) TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE NEW UNDESIRABLE EFFECTS 3) TO UPDATE SECTION 4.2 OF THE SMPC WITH ¿METHOD AND DURATION OF ADMINISTRATION¿ ADAPTING THE USE OF THE SYRINGE PUMP FOR SMALL VOLUMES ONLY. 4) TO UPDATE THE PRODUCT INFORMATION TEXT AND PIL IN LINE WITH THE ORIGINATOR FOR PROPOFOL 1% AND 2% IS DISOPRIVAN 1% BY ZENECA AND FOR ROPOFOL 0.5 % IS DISOPRIVAN 1%, EMULSION FOR INJECTION OR INFUSION BY ZENECA. ADDITIONALLY THE PRODUCT INFORMATION HAVE BEEN UPDATED IN IN LINE WITH EXCIPIENT

										GUIDELINE AND QRD TEMPLATE.
PL 03551/0113	PROPOFOL-LIPURO 0.5% (5MG/ML) EMULSION FOR INJECTION OR INFUSION	GRANTED	PL 03551/0113-0033	PL 03551/0113-0033	19/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4 OF THE SMPC TO INCLUDE NE WARNING CONCERNING DOSE REDUCTION IN PATIENTS WITH HYPOPROTEINAEMIA. 2) TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE NEW UNDESIRABLE EFFECTS 3) TO UPDATE SECTION 4.2 OF THE SMPC WITH ¿METHOD AND DURATION OF ADMINISTRATION¿ ADAPTING THE USE OF THE SYRINGE PUMP FOR SMALL VOLUMES ONLY. 4) TO UPDATE THE PRODUCT INFORMATION TEXT AND PIL IN LINE WITH THE ORIGINATOR FOR PROPOFOL 1% AND 2% IS DISOPRIVAN 1% BY ZENECA AND FOR ROPOFOL 0.5 % IS DISOPRIVAN 1%, EMULSION FOR INJECTION OR INFUSION BY ZENECA. ADDITIONALLY THE PRODUCT INFORMATION HAVE BEEN UPDATED IN IN LINE WITH EXCIPIENT

										GUIDELINE AND QRD TEMPLATE.
PL 18952/0004	HEXVIX 85 MG, POWDER AND SOLVENT FOR INTRAVESICAL SOLUTION	GRANTED	PL 18952/0004-0010	PL 18952/0004-0010	24/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 AND 5.1 OF THE SPC TO BRING IN LINE WITH RESULTS FROM STUDY PC B308/13, PRIMARILY TO DELETE THE STATEMENT THAT NO SPECIFIC STUDIES WITH REPETITIVE USE OF HEXVIX HAVE BEEN CONDUCTED AND FOLLOWING THE PERIODIC BENEFIT-RISK EVALUATION REPORT/PERIODIC SAFETY UPDATE REPORT (PSUR) NO 19, PSUSA/00001606/201909 FOR HEXVIX. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 05293/0008	ENSTILAR 50 MICROGRAMS/G + 0.5 MG/G CUTANEOUS FOAM	GRANTED	PL 05293/0008-0038	PL 05293/0008-0038	25/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC TO ADD 'APPLICATION SITE ERYTHEMA' AS AN AE, WITH THE FREQUENCY NOT KNOWN. THIS FOLLOWS ON FROM A REQUEST TO PERFORM PROPER SIGNAL ANALYSIS, INCLUDING DATA FROM STUDIES, LITERATURE, AND CASE REPORTS. TO ALSO

										UPDATE SECTION 2, 4.7, AND 4.9 OF THE SPC IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00057/0529	KETALAR 10 MG/ML INJECTION	GRANTED	PL 00057/0529-0074	PL 00057/0529-0074	26/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH THE MAH'S CCDS. THERE ARE NO CHANGES TO THE UK LEAFLET.
PL 00057/0530	KETALAR 50 MG/ML INJECTION	GRANTED	PL 00057/0530-0073	PL 00057/0530-0073	26/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH THE MAH'S CCDS. THERE ARE NO CHANGES TO THE UK LEAFLET.
PL 00057/0531	KETALAR 100 MG/ML INJECTION	GRANTED	PL 00057/0531-0071	PL 00057/0531-0071	26/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH THE MAH'S CCDS. THERE ARE NO CHANGES TO THE UK LEAFLET.
PL 29831/0736	WOCKAIR 160 MICROGRAMS/4.5 MICROGRAMS, INHALATION POWDER	GRANTED	PL 29831/0736-0014	PL 29831/0736-0014	26/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FROM VERSION 1.8.2 TO VERSION 2.1 O ADDRESS THE RMS COMMENTS AS RECEIVED IN DAY 70 PRELIMINARY ASSESSMENT REPORT DATED 20 MAY 2020

										UNDER PROCEDURE SE/H/1688-1690/002/DC.
PL 00242/0186	RISPERDAL 1MG FILM-COATED TABLETS	GRANTED	PL 00242/0186-0179	PL 00242/0186-0179	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8: 4.8 UNDESIRABLE EFFECTS SKIN AND SUBCUTANEOUS TISSUE DISORDERS: STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS - NOT KNOWN
PL 00242/0187	RISPERDAL 2MG FILM-COATED TABLETS	GRANTED	PL 00242/0187-0182	PL 00242/0187-0182	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8: 4.8 UNDESIRABLE EFFECTS SKIN AND SUBCUTANEOUS TISSUE DISORDERS: STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS - NOT KNOWN
PL 00242/0188	RISPERDAL 3MG FILM-COATED TABLETS	GRANTED	PL 00242/0188-0181	PL 00242/0188-0181	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8:

								RD) - CMS WORKSHARING		4.8 UNDESIRABLE EFFECTS SKIN AND SUBCUTANEOUS TISSUE DISORDERS: STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS - NOT KNOWN
PL 00242/0189	RISPERDAL 4MG FILM-COATED TABLETS	GRANTED	PL 00242/0189-0179	PL 00242/0189-0179	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8: 4.8 UNDESIRABLE EFFECTS SKIN AND SUBCUTANEOUS TISSUE DISORDERS: STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS - NOT KNOWN
PL 00242/0199	RISPERDAL 1MG/ML ORAL SOLUTION	GRANTED	PL 00242/0199-0170	PL 00242/0199-0170	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8: 4.8 UNDESIRABLE EFFECTS SKIN AND SUBCUTANEOUS TISSUE DISORDERS: STEVENS-JOHNSON

										SYNDROME/TOXIC EPIDERMAL NECROLYSIS - NOT KNOWN
PL 00242/0317	RISPERDAL 6MG FILM-COATED TABLETS	GRANTED	PL 00242/0317-0142	PL 00242/0317-0142	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8: 4.8 UNDESIRABLE EFFECTS SKIN AND SUBCUTANEOUS TISSUE DISORDERS: STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS - NOT KNOWN
PL 00242/0347	RISPERDAL 0.5MG FILM-COATED TABLETS	GRANTED	PL 00242/0347-0148	PL 00242/0347-0148	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8: 4.8 UNDESIRABLE EFFECTS SKIN AND SUBCUTANEOUS TISSUE DISORDERS: STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS - NOT KNOWN

PL 00242/0375	RISPERDAL CONSTA 25MG POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INTRAMUSCULAR INJECT	GRANTED	PL 00242/0375-0146	PL 00242/0375-0146	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8: 4.8 UNDESIRABLE EFFECTS SKIN AND SUBCUTANEOUS TISSUE DISORDERS: STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS - NOT KNOWN
PL 00242/0376	RISPERDAL CONSTA 37.5MG POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INTRAMUSCULAR INJECT	GRANTED	PL 00242/0376-0144	PL 00242/0376-0144	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8: 4.8 UNDESIRABLE EFFECTS SKIN AND SUBCUTANEOUS TISSUE DISORDERS: STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS - NOT KNOWN
PL 00242/0377	RISPERDAL CONSTA 50MG POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR	GRANTED	PL 00242/0377-0142	PL 00242/0377-0142	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8: 4.8 UNDESIRABLE EFFECTS

	INTRAMUSCULAR INJECT							WORKSHARING		SKIN AND SUBCUTANEOUS TISSUE DISORDERS: STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS - NOT KNOWN
PL 00289/0597	MOXONIDINE 300 MICROGRAM TABLETS	GRANTED	PL 00289/0597-0047	PL 00289/0597-0047	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2-4.6, 4.8, 5.1-5.3 AND 6.6 OF THE SMPC AND PIL IN LINE WITH REFERENCE PRODUCT FOR MOXONIDINE 0.2MG, 0.3MG AND 0.4MG FILM-COATED TABLETS.
PL 00289/0598	MOXONIDINE 400 MICROGRAM TABLETS	GRANTED	PL 00289/0598-0047	PL 00289/0598-0047	31/08/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2-4.6, 4.8, 5.1-5.3 AND 6.6 OF THE SMPC AND PIL IN LINE WITH REFERENCE PRODUCT FOR MOXONIDINE 0.2MG, 0.3MG AND 0.4MG FILM-COATED TABLETS.
PL 13606/0227	DUTASTERIDE STRIDES 0.5MG CAPSULES, SOFT	GRANTED	PL 13606/0227-0014	PL 13606/0227-0014	01/09/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) ¿ CMS RMP	MUTUAL RECOGNITION	TO UPDATE THE RMP FOR DUSTASTERIDE 0.5 MG SOFT CAPSULES WITH DATA LOCK POINT JULY 31ST, 2014, VERSION 02 TO RMP WITH DATA LOCK POINT APRIL 22ND, 2021 VERSION 0.1.
PL 37071/0024	DESFLURANE 100% V/V INHALATION VAPOUR, LIQUID	GRANTED	PL 37071/0024-0020	PL 37071/0024-0020	02/09/2022	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT SUPRANE.

										CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
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