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 12308/0016	DOTAREM 279.32 MG/ML SOLUTION FOR INJECTION, IN GLASS VIALS	GRANTED	PL 12308/0016-0087	PL 12308/0016-0087	04/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FROM VERSION 13 TO VERSION 14.
PL 12308/0017	DOTAREM 279.32 MG/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGES	GRANTED	PL 12308/0017-0086	PL 12308/0017-0086	04/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FROM VERSION 13 TO VERSION 14.
PL 00025/0610	INEGY 10MG/20MG TABLETS	GRANTED	PL 00025/0610-0037	PL 00025/0610-0037	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-4, 4-5 AND PIL IN LINE WITH CHANGES TO THE CCDS CONCERNING INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMGCOA REDUCTASE

										INHIBITORS AND DAPTOMYCIN. THE APPLICANT WOULD ALSO LIKE TO TAKE THIS OPPORTUNITY TO UPDATE SECTION 6 OF THE PATIENT LEAFLET BY REMOVING REFERENCES TO MEMBER STATES WHERE THE MARKETING AUTHORISATION OF INEGY (DE/H/0496/001-004) OR VYTORIN (DE/H/0493/001-004) HAVE BEEN WITHDRAWN
PL 00025/0611	INEGY 10MG/40MG TABLETS	GRANTED	PL 00025/0611-0040	PL 00025/0611-0040	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-4, 4-5 AND PIL IN LINE WITH CHANGES TO THE CCDS CONCERNING INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMGCOA REDUCTASE INHIBITORS AND DAPTOMYCIN. THE APPLICANT

										WOULD ALSO LIKE TO TAKE THIS OPPORTUNITY TO UPDATE SECTION 6 OF THE PATIENT LEAFLET BY REMOVING REFERENCES TO MEMBER STATES WHERE THE MARKETING AUTHORISATION OF INEGY (DE/H/0496/001-004) OR VYTORIN (DE/H/0493/001-004) HAVE BEEN WITHDRAWN
PL 00025/0612	INEGY 10MG/80MG TABLETS	GRANTED	PL 00025/0612-0042	PL 00025/0612-0042	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-4, 4-5 AND PIL IN LINE WITH CHANGES TO THE CCDS CONCERNING INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMGCOA REDUCTASE INHIBITORS AND DAPTOMYCIN. THE APPLICANT WOULD ALSO LIKE TO TAKE THIS OPPORTUNITY TO UPDATE SECTION 6 OF THE PATIENT LEAFLET BY REMOVING

										REFERENCES TO MEMBER STATES WHERE THE MARKETING AUTHORISATION OF INEGY (DE/H/0496/001-004) OR VYTORIN (DE/H/0493/001-004) HAVE BEEN WITHDRAWN
PL 21727/0032	PALEXIA 50 MG FILM-COATED TABLETS	GRANTED	PL 21727/0032-0042	PL 21727/0032-0042	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS DESCRIBED IN GVP MODULE V.
PL 21727/0033	PALEXIA 75 MG FILM-COATED TABLETS	GRANTED	PL 21727/0033-0043	PL 21727/0033-0043	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS

										DESCRIBED IN GVP MODULE V.
PL 21727/0034	PALEXIA 100 MG FILM-COATED TABLETS	GRANTED	PL 21727/0034-0044	PL 21727/0034-0044	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS DESCRIBED IN GVP MODULE V.
PL 21727/0041	PALEXIA SR 50 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0041-0047	PL 21727/0041-0047	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS DESCRIBED IN GVP MODULE V.
PL 21727/0042	PALEXIA SR 100 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0042-0047	PL 21727/0042-0047	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO

										UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS DESCRIBED IN GVP MODULE V.
PL 21727/0043	PALEXIA SR 150 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0043-0046	PL 21727/0043-0046	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS DESCRIBED IN GVP MODULE V.
PL 21727/0044	PALEXIA SR 200 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0044-0046	PL 21727/0044-0046	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS DESCRIBED IN GVP MODULE V.

PL 21727/0045	PALEXIA SR 250 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0045-0047	PL 21727/0045-0047	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS DESCRIBED IN GVP MODULE V.
PL 21727/0051	PALEXIA SR 25 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0051-0039	PL 21727/0051-0039	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS DESCRIBED IN GVP MODULE V.
PL 21727/0053	PALEXIA 4MG/ML ORAL SOLUTION	GRANTED	PL 21727/0053-0028	PL 21727/0053-0028	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP

										V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS DESCRIBED IN GVP MODULE V.
PL 21727/0054	PALEXIA 20MG/ML ORAL SOLUTION	GRANTED	PL 21727/0054-0029	PL 21727/0054-0029	05/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO V9.0 TO IMPLEMENT CHANGES TO AGREED POST-AUTHORISATION STUDIES AND TO UPDATE THE LIST OF SAFETY CONCERNS IN THE RMP. THE RMP V9.0 HAS BEEN FORMATTED TO REFLECT THE LATEST RMP TEMPLATE AS DESCRIBED IN GVP MODULE V.
PL 48221/0001	VENTIZOLVE 1.26 MG NASAL SPRAY, SOLUTION IN SINGLE-DOSE CONTAINER	GRANTED	PL 48221/0001-0003	PL 48221/0001-0003	09/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO ASSESS THE STUDY PROTOCOL WHICH INVESTIGATES THE EFFECTIVENESS AND SAFETY OF VENTIZOLVE ADMINISTRATION BY LAY PEOPLE IN REVERSING OPIOID OVERDOSE AS COMMITTED IN THE DAY 210 FINAL AR.
PL 04515/0098	ACICLOVIR 25 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 04515/0098-0093	PL 04515/0098-0093	09/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 1, 4.1, 4.2, 4.5, 4.6, 4.8, 4.9, 5.1, 5.2 AND 9 OF THE SMPC IN LINE WITH THE COMPANY CORE SAFETY

										INFORMATION, TO INCLUDE THE ADVERSE EVENT: STEPHEN JOHNSON SYNDROME. MINOR EDITORIAL CHANGES ARE INCLUDED IN THE SMPC AND THE PIL TO BRING IN LINE WITH THE LATEST QRD TEMPLATE.
PL 04425/0643	CORDARONE X 150MG/3ML SOLUTION FOR INJECTION	GRANTED	PL 04425/0643-0051	PL 04425/0643-0051	11/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC TO IMPLEMENT THE UPDATE OF THE COMPANY CORE DATA SHEET (CCDS) 21 OF AMIODARONE. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04569/1496	METHYLPHENIDATE HYDROCHLORIDE 5 MG TABLETS	GRANTED	PL 04569/1496-0012	PL 04569/1496-0012	11/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4, 4.6, 4.8, 4.9 AND 5.2 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT WHICH IS REGISTERED NATIONALLY (RITALIN® FROM NOVARTIS SVERIGE AB) AND ALSO SOME UPDATES IN LINE

										WITH QRD AND EDITORIAL UPDATES.
PL 04569/1497	METHYLPHENIDATE HYDROCHLORIDE 10 MG TABLETS	GRANTED	PL 04569/1497-0012	PL 04569/1497-0012	11/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4, 4.6, 4.8, 4.9 AND 5.2 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT WHICH IS REGISTERED NATIONALLY (RITALIN® FROM NOVARTIS SVERIGE AB) AND ALSO SOME UPDATES IN LINE WITH QRD AND EDITORIAL UPDATES.
PL 04569/1498	METHYLPHENIDATE HYDROCHLORIDE 20 MG TABLETS	GRANTED	PL 04569/1498-0012	PL 04569/1498-0012	11/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4, 4.6, 4.8, 4.9 AND 5.2 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT WHICH IS REGISTERED NATIONALLY (RITALIN® FROM NOVARTIS SVERIGE AB) AND ALSO SOME UPDATES IN LINE WITH QRD AND EDITORIAL UPDATES.
PL 15490/0001	SIMALVIA 60 MG/300 MG, SOFT CAPSULES	GRANTED	PL 15490/0001-0022	PL 15490/0001-0022	12/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.7, 4.8 AND 4.9 OF THE SMPC AND PIL FOR SIMALVIA, IN LINE WITH THE TEXT APPROVED IN FRANCE, AS COUNTRY OF ORIGIN, IN ORDER

										TO TAKE INTO ACCOUNT THE ADDITIONAL INFORMATION AND ALIGN LABELLINGS OF ALVERINE CITRATE AND SIMETICONE PRODUCTS.
PL 40431/0028	ARMONEVE 2.5 MG/1.25 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0028-0007	PL 40431/0028-0007	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE

										PIL HAS BEEN UPDATED.
PL 40431/0028	ARMONEVE 2.5 MG/1.25 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0028-0007	PL 40431/0028-0007	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0029	ARMONEVE 5 MG/2.5MG	GRANTED	PL 40431/0	PL 40431/0	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC

	PROLONGED-RELEASE TABLETS		029-0006	029-0006				(STANDARD) - CMS GROUPING		IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0029	ARMONEVE 5 MG/2.5MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0029-0006	PL 40431/0029-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017).

										[2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0030	ARMONEVE 10 MG/5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0030-0006	PL 40431/0030-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE

										OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0030	ARMONEVE 10 MG/5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0030-0006	PL 40431/0030-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS.

										ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0031	ARMONEVE 15 MG/7.5 MG PROLONGED-RELEASE TABLET	GRANTED	PL 40431/0031-0006	PL 40431/0031-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE

										LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0031	ARMONEVE 15 MG/7.5 MG PROLONGED-RELEASE TABLET	GRANTED	PL 40431/0031-0006	PL 40431/0031-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 40431/0032	ARMONEVE 20MG/10 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0032-0006	PL 40431/0032-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0032	ARMONEVE 20MG/10 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0032-0006	PL 40431/0032-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8

								GROUPING		AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0033	ARMONEVE 30MG/15MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0033-0006	PL 40431/0033-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT

										CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0033	ARMONEVE 30MG/15MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0033-0006	PL 40431/0033-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE

										PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0034	ARMONEVE 40MG/20MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0034-0006	PL 40431/0034-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION

										4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 40431/0034	ARMONEVE 40MG/20MG PROLONGED-RELEASE TABLETS	GRANTED	PL 40431/0034-0006	PL 40431/0034-0006	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	[1] TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 5.1 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEETS (VERSION 8 AND 9 RESPECTIVELY DATED 05 MAY 2016 AND 07 APRIL 2017). [2] TO UPDATE THE SMPC TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS. ADDITIONALLY, THE EXISING LACTOSE WARNING IN SECTION 4.4 OF THE SMPC HAS BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE.

										CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00006/0375	STRATTERA 10MG CAPSULES	GRANTED	PL 00006/0375-0110	PL 00006/0375-0110	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE CHANGES TO THE EU RMP FOLLOWING THE COMPLETION OF THE RENEWAL PROCEDURE FOR STRATTERA ORAL SOLUTION (ES/H/0575/009/R/03) AND THE COMPLETION OF 2 PASS STUDIES.
PL 00006/0376	STRATTERA 18MG CAPSULES	GRANTED	PL 00006/0376-0110	PL 00006/0376-0110	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE CHANGES TO THE EU RMP FOLLOWING THE COMPLETION OF THE RENEWAL PROCEDURE FOR STRATTERA ORAL SOLUTION (ES/H/0575/009/R/03) AND THE COMPLETION OF 2 PASS STUDIES.
PL 00006/0377	STRATTERA 25MG CAPSULES	GRANTED	PL 00006/0377-0110	PL 00006/0377-0110	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE CHANGES TO THE EU RMP FOLLOWING THE COMPLETION OF THE RENEWAL PROCEDURE FOR STRATTERA ORAL SOLUTION (ES/H/0575/009/R/03) AND THE COMPLETION OF 2 PASS STUDIES.
PL 00006/0378	STRATTERA 40MG CAPSULES	GRANTED	PL 00006/0	PL 00006/0	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO INTRODUCE CHANGES TO THE EU RMP FOLLOWING THE

			378-0110	378-0110				(STANDARD) - CMS		COMPLETION OF THE RENEWAL PROCEDURE FOR STRATTERA ORAL SOLUTION (ES/H/0575/009/R/03) AND THE COMPLETION OF 2 PASS STUDIES.
PL 00006/0379	STRATTERA 60MG CAPSULES	GRANTED	PL 00006/0379-0110	PL 00006/0379-0110	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE CHANGES TO THE EU RMP FOLLOWING THE COMPLETION OF THE RENEWAL PROCEDURE FOR STRATTERA ORAL SOLUTION (ES/H/0575/009/R/03) AND THE COMPLETION OF 2 PASS STUDIES.
PL 00006/0615	STRATTERA 80MG HARD CAPSULES	GRANTED	PL 00006/0615-0076	PL 00006/0615-0076	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE CHANGES TO THE EU RMP FOLLOWING THE COMPLETION OF THE RENEWAL PROCEDURE FOR STRATTERA ORAL SOLUTION (ES/H/0575/009/R/03) AND THE COMPLETION OF 2 PASS STUDIES.
PL 00006/0616	STRATTERA 100MG HARD CAPSULES	GRANTED	PL 00006/0616-0080	PL 00006/0616-0080	16/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE CHANGES TO THE EU RMP FOLLOWING THE COMPLETION OF THE RENEWAL PROCEDURE FOR STRATTERA ORAL SOLUTION (ES/H/0575/009/R/03)

										AND THE COMPLETION OF 2 PASS STUDIES.
PL 19494/0252	TOCTINO 10MG SOFT CAPSULES	GRANTED	PL 19494/0252-0027	PL 19494/0252-0027	17/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP FROM VERSION NUMBER 8 TO VERSION NUMBER 11, IN LINE WITH THE CURRENT PHARMACOVIGILANCE LEGISLATION AND THE PRAC RECOMMENDATION AND POST APPROVAL COMMITMENTS PROPOSED IN THE ARTICLE 31 PROCEDURE RETINOID CONTAINING MEDICINAL PRODUCTS, [EMEA/H/A-31/1446].
PL 19494/0253	TOCTINO 30MG SOFT CAPSULES	GRANTED	PL 19494/0253-0027	PL 19494/0253-0027	17/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP FROM VERSION NUMBER 8 TO VERSION NUMBER 11, IN LINE WITH THE CURRENT PHARMACOVIGILANCE LEGISLATION AND THE PRAC RECOMMENDATION AND POST APPROVAL COMMITMENTS PROPOSED IN THE ARTICLE 31 PROCEDURE RETINOID

										CONTAINING MEDICINAL PRODUCTS, [EMEA/H/A-31/1446].
PL 17901/0002	ARIMIDEX 1MG FILM-COATED TABLETS	GRANTED	PL 17901/0002-0095	PL 17901/0002-0095	18/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REGISTER AN UPDATED RISK MANAGEMENT PLAN (RMP) FOR WHICH COMMITMENT WAS ALREADY MADE IN PSUSA PROCEDURE (PSUSA/00000210/201708). IN ADDITION, UPDATES TO THE FORMAT AND CONTENT WERE MADE TO ALL SECTIONS OF THIS RMP IN LINE WITH THE REQUIREMENTS OF THE REVISED RMP TEMPLATE FOLLOWING THE RELEASE OF THE REVISED 'GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES: MODULE V ¿ RISK MANAGEMENT SYSTEMS (REV. 2)¿.
PL 04539/0014	TRANSTEC 35 MICROGRAMS/H TRANSDERMAL PATCH	GRANTED	PL 04539/0014-0063	PL 04539/0014-0063	20/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC BASED ON THE CMDH RECOMMENDATION ON CONCOMITANT USE OF BENZODIAZEPINES

										AND OPIOIDS. [2] TO UPDATE SECTION 4.6 OF THE SMPC TO REMOVE INFORMATION ON THE FERTILITY OF ANIMALS AND REPLACE WITH INFORMATION ON THE FERTILITY OF HUMANS, BASED ON THE NTA "A GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)", DATED SEPTEMBER 2009. [3] TO UPDATE SECTION 5.3 OF THE SMPC TO INCLUDE MORE DETAIL REGARDING PRE-CLINICAL INFORMATION. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 04539/0014	TRANSTEC 35 MICROGRAMS/H TRANSDERMAL PATCH	GRANTED	PL 04539/0014-0063	PL 04539/0014-0063	20/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC BASED ON THE CMDH RECOMMENDATION ON CONCOMITANT USE OF BENZODIAZEPINES AND OPIOIDS.

										[2] TO UPDATE SECTION 4.6 OF THE SMPC TO REMOVE INFORMATION ON THE FERTILITY OF ANIMALS AND REPLACE WITH INFORMATION ON THE FERTILITY OF HUMANS, BASED ON THE NTA "A GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)", DATED SEPTEMBER 2009. [3] TO UPDATE SECTION 5.3 OF THE SMPC TO INCLUDE MORE DETAIL REGARDING PRE-CLINICAL INFORMATION. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 04539/0015	TRANSTEC 52.5 MICROGRAMS/H TRANSDERMAL PATCH	GRANTED	PL 04539/0015-0064	PL 04539/0015-0064	20/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC BASED ON THE CMDH RECOMMENDATION ON CONCOMITANT USE OF BENZODIAZEPINES AND OPIOIDS.

										[2] TO UPDATE SECTION 4.6 OF THE SMPC TO REMOVE INFORMATION ON THE FERTILITY OF ANIMALS AND REPLACE WITH INFORMATION ON THE FERTILITY OF HUMANS, BASED ON THE NTA "A GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)", DATED SEPTEMBER 2009. [3] TO UPDATE SECTION 5.3 OF THE SMPC TO INCLUDE MORE DETAIL REGARDING PRE-CLINICAL INFORMATION. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 04539/0015	TRANSTEC 52.5 MICROGRAMS/H TRANSDERMAL PATCH	GRANTED	PL 04539/0015-0064	PL 04539/0015-0064	20/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC BASED ON THE CMDH RECOMMENDATION ON CONCOMITANT USE OF BENZODIAZEPINES AND OPIOIDS. [2] TO UPDATE

										SECTION 4.6 OF THE SMPC TO REMOVE INFORMATION ON THE FERTILITY OF ANIMALS AND REPLACE WITH INFORMATION ON THE FERTILITY OF HUMANS, BASED ON THE NTA "A GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)", DATED SEPTEMBER 2009. [3] TO UPDATE SECTION 5.3 OF THE SMPC TO INCLUDE MORE DETAIL REGARDING PRE-CLINICAL INFORMATION. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 04539/0016	TRANSTEC 70 MICROGRAMS/H TRANSDERMAL PATCH	GRANTED	PL 04539/0016-0065	PL 04539/0016-0065	20/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC BASED ON THE CMDH RECOMMENDATION ON CONCOMITANT USE OF BENZODIAZEPINES AND OPIOIDS. [2] TO UPDATE SECTION 4.6 OF THE

										SMPC TO REMOVE INFORMATION ON THE FERTILITY OF ANIMALS AND REPLACE WITH INFORMATION ON THE FERTILITY OF HUMANS, BASED ON THE NTA "A GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)", DATED SEPTEMBER 2009. [3] TO UPDATE SECTION 5.3 OF THE SMPC TO INCLUDE MORE DETAIL REGARDING PRE-CLINICAL INFORMATION. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 04539/0016	TRANSTEC 70 MICROGRAMS/H TRANSDERMAL PATCH	GRANTED	PL 04539/0016-0065	PL 04539/0016-0065	20/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC BASED ON THE CMDH RECOMMENDATION ON CONCOMITANT USE OF BENZODIAZEPINES AND OPIOIDS. [2] TO UPDATE SECTION 4.6 OF THE SMPC TO REMOVE

										INFORMATION ON THE FERTILITY OF ANIMALS AND REPLACE WITH INFORMATION ON THE FERTILITY OF HUMANS, BASED ON THE NTA "A GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)", DATED SEPTEMBER 2009. [3] TO UPDATE SECTION 5.3 OF THE SMPC TO INCLUDE MORE DETAIL REGARDING PRE-CLINICAL INFORMATION. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 17780/0500	CO-CODAMOL 15/500 TABLETS	GRANTED	PL 17780/0500-0041	PL 17780/0500-0041	20/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	DECENTRALISED	TO UPDATE SECTION 4.9 OF THE SPC DUE TO NEW CLINICAL DATA.
PL 04416/1040	CYPROTERONE ACETATE 2.0MG ETHINYLESTRADIOL 0.035MG TABLETS	GRANTED	PL 04416/1040-0022	PL 04416/1040-0022	20/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.8, 5.2, 5.3, 6.1 AND 6.5 OF THE SMPC IN LINE WITH THE NOT HARMONIZED REFERENCE PRODUCT, DIANE-35,

										0.035 MG/2 MG COATED TABLETS (MA NUMBER: 347.01.00 - MAH: JENAPHARM GMBH & CO. KG). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00057/1523	LIPITOR 10 MG FILM-COATED TABLETS	GRANTED	PL 00057/1523-0018	PL 00057/1523-0018	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION (DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE PACKAGE LEAFLET OF

										AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.
PL 00057/1524	LIPITOR 20 MG FILM-COATED TABLETS	GRANTED	PL 00057/1524-0017	PL 00057/1524-0017	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION (DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.

PL 00057/1525	LIPITOR 40 MG FILM-COATED TABLETS	GRANTED	PL 00057/1525-0017	PL 00057/1525-0017	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION (DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.
PL 00057/1526	LIPITOR 80 MG FILM-COATED TABLETS	GRANTED	PL 00057/1526-0017	PL 00057/1526-0017	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION

										(DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.
PL 00057/1527	LIPITOR 5MG CHEWABLE TABLET	GRANTED	PL 00057/1527-0013	PL 00057/1527-0013	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION (DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED

										TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.
PL 00057/1528	LIPITOR 10MG CHEWABLE TABLETS	GRANTED	PL 00057/1528-0013	PL 00057/1528-0013	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION (DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE

										PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.
PL 00057/1529	LIPITOR 20MG CHEWABLE TABLET	GRANTED	PL 00057/1529-0013	PL 00057/1529-0013	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION (DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.

PL 00057/1530	LIPITOR 40MG CHEWABLE TABLET	GRANTED	PL 00057/1530-0013	PL 00057/1530-0013	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION (DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.
PL 00057/1531	ATORVASTATIN 10 MG FILM COATED TABLETS	GRANTED	PL 00057/1531-0010	PL 00057/1531-0010	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION

										(DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.
PL 00057/1532	ATORVASTATIN 20 MG FILM COATED TABLETS	GRANTED	PL 00057/1532-0010	PL 00057/1532-0010	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION (DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED

										TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.
PL 00057/1533	ATORVASTATIN 40 MG FILM COATED TABLETS	GRANTED	PL 00057/1533-0010	PL 00057/1533-0010	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION (DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE

										PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.
PL 00057/1534	ATORVASTATIN 80 MG FILM COATED TABLETS	GRANTED	PL 00057/1534-0010	PL 00057/1534-0010	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.5 OF THE SPC FOLLOWING AN EVALUATION OF THE INFORMATION RELATED TO A POTENTIAL DRUG-DRUG INTERACTION (DDI) BETWEEN ATORVASTATIN AND LETERMOVIR. IN ADDITION, THE PIL HAS BEEN UPDATED TO IMPLEMENT THE OUTCOME OF THE PSUSA ON ATORVASTATIN/EZETIMIBE. ALSO, A TYPOGRAPHIC ERROR IS CORRECTED IN SECTION 2 OF THE PACKAGE LEAFLET OF AMLODIPINE/ATORVASTATIN PRODUCTS. FUSIDIC ACID WAS INCORRECTLY LISTED UNDER MACROLIDE ANTIBIOTICS.

PL 24837/0058	CILIQUE 250/35 MICROGRAM TABLETS	GRANTED	PL 24837/0058-0014	PL 24837/0058-0014	23/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5 AND 4.8 OF THE SMPC AND PIL IN LINE WITH THE EFERENCE PRODUCT CILEST 250/35 MICROGRAMS FILM-COATED TABLETS (MAH- JANSSEN-CILAG LIMITED)
PL 00289/1648	LOFAMIL XL 200 MG PROLONGED-RELEASE CAPSULES	GRANTED	PL 00289/1648-0015	PL 00289/1648-0015	24/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 AND 6.6 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT (TILDIEM LA 200/300 MG PROLONGED-RELEASE CAPSULES, HARD (SANOFI), UK.), FOLLOWING THE CSP UPDATE BASED ON THE PSUR ASSESSMENT REPORT DK/H/PSUR/0017/001, DATED 17.05.2010, AND IN LINE WITH THE QRD TEMPLATE. CONSEQUENTLY, THE PIL AND LABEL TEXTS* HAVE BEEN UPDATED. *THE LABEL TEXTS ALSO CONTAIN CHANGES APPROVED WITH UK/H/4669/001/P/001. THE COMMON PIL TEXT HAS BEEN

										INDEXED INTO M1. AS THE PRODUCT IS NOT MARKETED, A FULL 61(3) SUBMISSION WILL BE REQUIRED PRIOR TO MARKETING.
PL 00289/1648	LOFAMIL XL 200 MG PROLONGED-RELEASE CAPSULES	GRANTED	PL 00289/1648-0015	PL 00289/1648-0015	24/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 AND 6.6 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT (TILDIEM LA 200/300 MG PROLONGED-RELEASE CAPSULES, HARD (SANOFI), UK.), FOLLOWING THE CSP UPDATE BASED ON THE PSUR ASSESSMENT REPORT DK/H/PSUR/0017/001, DATED 17.05.2010, AND IN LINE WITH THE QRD TEMPLATE. CONSEQUENTLY, THE PIL AND LABEL TEXTS* HAVE BEEN UPDATED. *THE LABEL TEXTS ALSO CONTAIN CHANGES APPROVED WITH UK/H/4669/001/P/001. THE COMMON PIL TEXT HAS BEEN INDEXED INTO M1. AS THE PRODUCT IS NOT MARKETED, A FULL

										61(3) SUBMISSION WILL BE REQUIRED PRIOR TO MARKETING.
PL 00289/1649	LOFAMIL XL 300 MG PROLONGED-RELEASE CAPSULES	GRANTED	PL 00289/1649-0015	PL 00289/1649-0015	24/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 AND 6.6 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT (TILDIEM LA 200/300 MG PROLONGED-RELEASE CAPSULES, HARD (SANOFI), UK.), FOLLOWING THE CSP UPDATE BASED ON THE PSUR ASSESSMENT REPORT DK/H/PSUR/0017/001, DATED 17.05.2010, AND IN LINE WITH THE QRD TEMPLATE. CONSEQUENTLY, THE PIL AND LABEL TEXTS* HAVE BEEN UPDATED. *THE LABEL TEXTS ALSO CONTAIN CHANGES APPROVED WITH UK/H/4669/001/P/001. THE COMMON PIL TEXT HAS BEEN INDEXED INTO M1. AS THE PRODUCT IS NOT MARKETED, A FULL 61(3) SUBMISSION WILL BE REQUIRED

										PRIOR TO MARKETING.
PL 00289/1649	LOFAMIL XL 300 MG PROLONGED-RELEASE CAPSULES	GRANTED	PL 00289/1649-0015	PL 00289/1649-0015	24/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 AND 6.6 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT (TILDIEM LA 200/300 MG PROLONGED-RELEASE CAPSULES, HARD (SANOFI), UK.), FOLLOWING THE CSP UPDATE BASED ON THE PSUR ASSESSMENT REPORT DK/H/PSUR/0017/001, DATED 17.05.2010, AND IN LINE WITH THE QRD TEMPLATE. CONSEQUENTLY, THE PIL AND LABEL TEXTS* HAVE BEEN UPDATED. *THE LABEL TEXTS ALSO CONTAIN CHANGES APPROVED WITH UK/H/4669/001/P/001. THE COMMON PIL TEXT HAS BEEN INDEXED INTO M1. AS THE PRODUCT IS NOT MARKETED, A FULL 61(3) SUBMISSION WILL BE REQUIRED PRIOR TO MARKETING.

PL 17780/0259	SLOCINX XL 4MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17780/0259-0042	PL 17780/0259-0042	24/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT CARDURA XL 4 MG PROLONGED RELEASE TABLETS. CONSEQUENTIALLY THE PIL AND LABEL TEXTS HAVE ALSO BEEN UPDATED. MOCK-UPS HAVE NOT BEEN SUPPLIED HERE, BUT WILL BE FILED AS PART OF A SEPARATE PIQ SUBMISSION.
PL 04569/0848	PANTOPRAZOLE 20MG GASTRO-RESISTANT TABLETS	GRANTED	PL 04569/0848-0047	PL 04569/0848-0047	25/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE THE SMPC (SECTIONS 4.4, 4.5) AND PIL TEXT* FOLLOWING MYLAN¿S RECENT ACQUISITION OF THE MAH MEDA AND IN LINE WITH THE REFERENCE PRODUCT PROTIUM. *PRODUCTS NOT MARKETED NB: INITIAL CHANGE PROPOSED TO SPC 4.3 NOT ACCEPTED.
PL 04569/0848	PANTOPRAZOLE 20MG GASTRO-RESISTANT TABLETS	GRANTED	PL 04569/0	PL 04569/0	25/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE THE SMPC (SECTIONS 4.4, 4.5) AND PIL TEXT*

			848-0047	848-0047				(STANDARD) - RMS GROUPING		FOLLOWING MYLAN¿S RECENT ACQUISITION OF THE MAH MEDA AND IN LINE WITH THE REFERENCE PRODUCT PROTIUM. *PRODUCTS NOT MARKETED NB: INITIAL CHANGE PROPOSED TO SPC 4.3 NOT ACCEPTED.
PL 04569/0849	PANTOPRAZOLE 40MG GASTRO-RESISTANT TABLETS	GRANTED	PL 04569/0849-0053	PL 04569/0849-0053	25/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE THE SMPC (SECTIONS 4.4, 4.5) AND PIL TEXT* FOLLOWING MYLAN¿S RECENT ACQUISITION OF THE MAH MEDA AND IN LINE WITH THE REFERENCE PRODUCT PROTIUM. *PRODUCTS NOT MARKETED NB: INITIAL CHANGE PROPOSED TO SPC 4.3 NOT ACCEPTED.
PL 04569/0849	PANTOPRAZOLE 40MG GASTRO-RESISTANT TABLETS	GRANTED	PL 04569/0849-0053	PL 04569/0849-0053	25/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE THE SMPC (SECTIONS 4.4, 4.5) AND PIL TEXT* FOLLOWING MYLAN¿S RECENT ACQUISITION OF THE MAH MEDA

								GROUPING		AND IN LINE WITH THE REFERENCE PRODUCT PROTIUM. *PRODUCTS NOT MARKETED NB: INITIAL CHANGE PROPOSED TO SPC 4.3 NOT ACCEPTED.
PL 17901/0201	CRESTOR 10MG FILM-COATED TABLETS	GRANTED	PL 17901/0201-0125	PL 17901/0201-0125	25/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP FOR ROSUVASTATIN CALCIUM FROM VERSION 4.0 TO VERSION 5.0, IN LINE WITH (GVP) MODULE V, RISK MANAGEMENT SYSTEMS (REVISION 2) GUIDELINES.
PL 17901/0202	CRESTOR 20MG FILM-COATED TABLETS	GRANTED	PL 17901/0202-0125	PL 17901/0202-0125	25/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP FOR ROSUVASTATIN CALCIUM FROM VERSION 4.0 TO VERSION 5.0, IN LINE WITH (GVP) MODULE V, RISK MANAGEMENT SYSTEMS (REVISION 2) GUIDELINES.
PL 17901/0203	CRESTOR 40MG FILM-COATED TABLETS	GRANTED	PL 17901/0203-0123	PL 17901/0203-0123	25/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP FOR ROSUVASTATIN CALCIUM FROM VERSION 4.0 TO VERSION 5.0, IN LINE WITH (GVP) MODULE V, RISK MANAGEMENT SYSTEMS (REVISION 2) GUIDELINES.

PL 17901/0243	CRESTOR 5MG FILM-COATED TABLETS	GRANTED	PL 17901/0243-0119	PL 17901/0243-0119	25/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP FOR ROSUVASTATIN CALCIUM FROM VERSION 4.0 TO VERSION 5.0, IN LINE WITH (GVP) MODULE V, RISK MANAGEMENT SYSTEMS (REVISION 2) GUIDELINES.
PL 00063/0551	LEMSIP COUGH MAX FOR MUCUS COUGH & COLD 500MG/100MG/6.1MG CAPSULES	GRANTED	PL 00063/0551-0042	PL 00063/0551-0042	26/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE THE SPC (SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9) FOLLOWING A REVIEW OF THE CCDS AND IN LINE WITH THE CURRENT QRD TEMPLATE AND SPC GUIDANCE. CONSEQUENTIALLY, THE PIL* AND LABEL HAVE ALSO BEEN UPDATED. *PIL MOCK-UPS NOT SUPPLIED; TO BE FILED UNDER A SEPARATE SUBMISSION.
PL 00063/0551	LEMSIP COUGH MAX FOR MUCUS COUGH & COLD 500MG/100MG/6.1MG CAPSULES	GRANTED	PL 00063/0551-0042	PL 00063/0551-0042	26/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE THE SPC (SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9) FOLLOWING A REVIEW OF THE CCDS AND IN LINE WITH THE CURRENT QRD TEMPLATE AND SPC GUIDANCE. CONSEQUENTIALLY, THE PIL* AND LABEL

										HAVE ALSO BEEN UPDATED. *PIL MOCK-UPS NOT SUPPLIED; TO BE FILED UNDER A SEPARATE SUBMISSION.
PL 00063/0551	LEMSIP MAX ALL IN ONE COLD & FLU CAPSULES	GRANTED	PL 00063/0551-0042	PL 00063/0551-0042	26/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE THE SPC (SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9) FOLLOWING A REVIEW OF THE CCDS AND IN LINE WITH THE CURRENT QRD TEMPLATE AND SPC GUIDANCE. CONSEQUENTIALLY, THE PIL* AND LABEL HAVE ALSO BEEN UPDATED. *PIL MOCK-UPS NOT SUPPLIED; TO BE FILED UNDER A SEPARATE SUBMISSION.
PL 00063/0551	LEMSIP MAX ALL IN ONE COLD & FLU CAPSULES	GRANTED	PL 00063/0551-0042	PL 00063/0551-0042	26/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE THE SPC (SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9) FOLLOWING A REVIEW OF THE CCDS AND IN LINE WITH THE CURRENT QRD TEMPLATE AND SPC GUIDANCE. CONSEQUENTIALLY, THE PIL* AND LABEL HAVE ALSO BEEN

										UPDATED. *PIL MOCK-UPS NOT SUPPLIED; TO BE FILED UNDER A SEPARATE SUBMISSION.
PL 00025/0241	ZOCOR 10 MG, FILM-COATED TABLETS	GRANTED	PL 00025/0241-0156	PL 00025/0241-0156	27/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC TO INCLUDE TEXT REGARDING AN INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMGCOA REDUCTASE INHIBITORS AND DAPTOMYCIN (USED FOR TREATMENT OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS AND BACTERAEMIA). AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 00025/0242	ZOCOR 20 MG, FILM-COATED TABLETS	GRANTED	PL 00025/0242-0155	PL 00025/0242-0155	27/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC TO INCLUDE TEXT REGARDING AN INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMGCOA REDUCTASE INHIBITORS AND DAPTOMYCIN (USED

										FOR TREATMENT OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS AND BACTERAEMIA). AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 00025/0243	ZOCOR 40 MG, FILM-COATED TABLETS	GRANTED	PL 00025/0243-0151	PL 00025/0243-0151	27/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC TO INCLUDE TEXT REGARDING AN INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMGCOA REDUCTASE INHIBITORS AND DAPTOMYCIN (USED FOR TREATMENT OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS AND BACTERAEMIA). AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 00025/0366	ZOCOR 80 MG, FILM-COATED TABLETS	GRANTED	PL 00025/0366-0096	PL 00025/0366-0096	27/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC TO INCLUDE TEXT REGARDING AN INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMGCOA REDUCTASE INHIBITORS AND

										DAPTOMYCIN (USED FOR TREATMENT OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS AND BACTERAEMIA). AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 00116/0349	RINGER'S SOLUTION FOR INFUSION	GRANTED	PL 00116/0349-0058	PL 00116/0349-0058	27/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SPC SECTIONS 4.2, 4.4, 4.5, 4.6, AND 4.8 IN LINE WITH THE PRAC RECOMMENDATIONS ON SIGNALS FOR HYPONATRAEMIA (EMA/PRAC/406967/2017). ALSO, TO UPDATE SPC SECTIONS 4.3, 4.4, 4.7, 4.8, AND 4.9 IN LINE WITH THE CCSI AND QRD TEMPLATE. CONSEQUENTIALLY, THE PACKAGE LEAFLET HAS ALSO BEEN UPDATED. THE LABELLING WILL ALSO BE UPDATED IN LINE WITH THE QRD TEMPLATE.
PL 00116/0349	RINGER'S SOLUTION FOR INFUSION	GRANTED	PL 00116/0349-0058	PL 00116/0349-0058	27/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SPC SECTIONS 4.2, 4.4, 4.5, 4.6, AND 4.8 IN LINE WITH THE PRAC RECOMMENDATIONS ON SIGNALS FOR HYPONATRAEMIA (EMA/PRAC/406967/2017). ALSO, TO UPDATE

										SPC SECTIONS 4.3, 4.4, 4.7, 4.8, AND 4.9 IN LINE WITH THE CCSI AND QRD TEMPLATE. CONSEQUENTIALLY, THE PACKAGE LEAFLET HAS ALSO BEEN UPDATED. THE LABELLING WILL ALSO BE UPDATED IN LINE WITH THE QRD TEMPLATE.
PL 00063/0553	LEMSIP MAX BLACKCURRANT FLAVOUR TABLETS	GRANTED	PL 00063/0553-0013	PL 00063/0553-0013	30/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8 AND 4.9 OF THE SPC TO BRING IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS), FOLLOWING SUBMISSION OF THE LATEST PSUR FOR PARACETAMOL AND PHENYLEPHRINE. CONSEQUENTIALLY THE PIL AND LABEL WILL BE UPDATED. *FINAL UK NATIONAL PI NOT RECEIVED, WHICH SHOULD ALSO HAVE INCORPORATED CHANGES FROM TIB VARIATION APPROVED JAN.2019 (UK/H/1786/001/IB/015/G). DUE TO TIME CONSTRAINTS FROM IMPENDING BREXIT, THE PIL, LABEL, AND

										SPC FRAGMENTS FROM VARIATION WS/138 (EXCEPT 4.5, 4.6, & 4.9) HAVE BEEN INDEXED INTO 'INPUT' FOLDER. EMAIL SENT TO MAH INFORMING THEM TO FILE A SEPARATE SUBMISSION WITH UPDATED PI THAT CONSOLIDATES THE CHANGES ACROSS BOTH VARIATIONS.
PL 00063/0555	LEMSIP MAX LEMON FLAVOUR TABLETS	GRANTED	PL 00063/0555-0020	PL 00063/0555-0020	30/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8 AND 4.9 OF THE SPC TO BRING IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS), FOLLOWING SUBMISSION OF THE LATEST PSUR FOR PARACETAMOL AND PHENYLEPHRINE. CONSEQUENTIALLY THE PIL AND LABEL WILL BE UPDATED. *FINAL UK NATIONAL PI NOT RECEIVED, WHICH SHOULD ALSO HAVE INCORPORATED CHANGES FROM TIB VARIATION APPROVED FEB.2019 (UK/H/1787/001/IB/013/G). DUE TO TIME CONSTRAINTS FROM

										IMPENDING BREXIT, THE PIL, LABEL, AND SPC FRAGMENTS FROM WS/138 (EXCEPT 4.5 & 4.9) HAVE BEEN INDEXED INTO 'INPUT' FOLDER. EMAIL SENT TO MAH INFORMING THEM TO FILE A SEPARATE SUBMISSION WITH UPDATED PI THAT CONSOLIDATES THE CHANGES ACROSS BOTH VARIATIONS.
PL 00116/0336	POTASSIUM CHLORIDE 0.15% W/V & SODIUM CHLORIDE 0.9% W/V SOLUTION FOR INFUSION - BP	GRANTED	PL 00116/0336-0039	PL 00116/0336-0039	30/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 3*, 4.2-4.9, 6.6 OF THE SPC IN LINE WITH THE PRAC RECOMMENDATION EMA/PRAC/406987/2017, CCSI, AND QRD TEMPLATE. CONSEQUENTIALLY, THE PACKAGE LEAFLET HAS ALSO BEEN UPDATED. *APPLIES TO POTASSIUM CHLORIDE 0.3% & SODIUM CHLORIDE 0.9% SOLUTION FOR INFUSION ONLY.
PL 00116/0336	POTASSIUM CHLORIDE 0.15% W/V & SODIUM CHLORIDE 0.9% W/V SOLUTION FOR INFUSION - BP	GRANTED	PL 00116/0336-0039	PL 00116/0336-0039	30/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 3*, 4.2-4.9, 6.6 OF THE SPC IN LINE WITH THE PRAC RECOMMENDATION

								RMS WORKSHARING		EMA/PRAC/406987/2017, CCSI, AND QRD TEMPLATE. CONSEQUENTIALLY, THE PACKAGE LEAFLET HAS ALSO BEEN UPDATED. *APPLIES TO POTASSIUM CHLORIDE 0.3% & SODIUM CHLORIDE 0.9% SOLUTION FOR INFUSION ONLY.
PL 00116/0337	POTASSIUM CHLORIDE 0.3% & SODIUM CHLORIDE 0.9% SOLN FOR INFU	GRANTED	PL 00116/0337-0046	PL 00116/0337-0046	30/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 3*, 4.2-4.9, 6.6 OF THE SPC IN LINE WITH THE PRAC RECOMMENDATION EMA/PRAC/406987/2017, CCSI, AND QRD TEMPLATE. CONSEQUENTIALLY, THE PACKAGE LEAFLET HAS ALSO BEEN UPDATED. *APPLIES TO POTASSIUM CHLORIDE 0.3% & SODIUM CHLORIDE 0.9% SOLUTION FOR INFUSION ONLY.
PL 00116/0337	POTASSIUM CHLORIDE 0.3% & SODIUM CHLORIDE 0.9% SOLN FOR INFU	GRANTED	PL 00116/0337-0046	PL 00116/0337-0046	30/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 3*, 4.2-4.9, 6.6 OF THE SPC IN LINE WITH THE PRAC RECOMMENDATION EMA/PRAC/406987/201

								WORKSHARING		7, CCSI, AND QRD TEMPLATE. CONSEQUENTIALLY, THE PACKAGE LEAFLET HAS ALSO BEEN UPDATED. *APPLIES TO POTASSIUM CHLORIDE 0.3% & SODIUM CHLORIDE 0.9% SOLUTION FOR INFUSION ONLY.
PL 02855/0245	PARACETAMOL AND CODEINE PHOSPHATE OMEGA 500MG/12.8MG FILM-COATED TABLETS	GRANTED	PL 02855/0245-0005	PL 02855/0245-0005	30/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.8 AND 4.9 OF THE SMPC AND PIL IN ORDER TO ADAPT TO A RECOMMENDATION OF A COMPETENT AUTHORITY. PRAC RECOMMENDATION ON PARACETAMOL - DRUG-INDUCED STEVENS-JOHNSON SYNDROME (SJS), TOXIC EPIDERMAL NECROLYSIS (TEN), AND ACUTE GENERALISED EXANTHEMATOUS PUSTULOSIS (AGEP) ADOPTED ON 6 FEBRUARY 2014 (EMA/PRAC/65788/2014).

										2) TO UPDATE THE SMPC AND PACKAGE LEAFLET OF HUMAN MEDICINAL PRODUCTS IN ORDER TO ADAPT TO A RECOMMENDATION OF A COMPETENT AUTHORITY. CMDH ADVICE ON CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS (CMDH/372/2018). 3) TO UPDATE SECTIONS 4.2 AND 4.4 OF THE SMPC TO ADD THE ADVICE TO PATIENTS USING THIS PRODUCT WITH HEPATIC IMPAIRMENT AND/OR RENAL IMPAIRMENT. 4) TO UPDATE SECTION 4.4 TO CORRECT THE STATEMENT REGARDING USE OF PARACETAMOL IN PATIENTS WITH

										HEPATOCELLULAR INSUFFICIENCY. 5) TO UPDATE SECTION 4.9 OF THE SMPC TO ADD THE INFORMATION REGARDING POSSIBLE LIVER DAMAGE AND SYMPTOMS OF ACUTE RENAL FAILURE.
PL 02855/0245	PARACETAMOL AND CODEINE PHOSPHATE OMEGA 500MG/12.8MG FILM-COATED TABLETS	GRANTED	PL 02855/0245-0005	PL 02855/0245-0005	30/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.8 AND 4.9 OF THE SMPC AND PIL IN ORDER TO ADAPT TO A RECOMMENDATION OF A COMPETENT AUTHORITY. PRAC RECOMMENDATION ON PARACETAMOL - DRUG-INDUCED STEVENS-JOHNSON SYNDROME (SJS), TOXIC EPIDERMAL NECROLYSIS (TEN), AND ACUTE GENERALISED EXANTHEMATOUS PUSTULOSIS (AGEP) ADOPTED ON 6 FEBRUARY 2014 (EMA/PRAC/65788/2014).

										2) TO UPDATE THE SMPC AND PACKAGE LEAFLET OF HUMAN MEDICINAL PRODUCTS IN ORDER TO ADAPT TO A RECOMMENDATION OF A COMPETENT AUTHORITY. CMDH ADVICE ON CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS (CMDH/372/2018). 3) TO UPDATE SECTIONS 4.2 AND 4.4 OF THE SMPC TO ADD THE ADVICE TO PATIENTS USING THIS PRODUCT WITH HEPATIC IMPAIRMENT AND/OR RENAL IMPAIRMENT. 4) TO UPDATE SECTION 4.4 TO CORRECT THE STATEMENT REGARDING USE OF PARACETAMOL IN PATIENTS WITH

										HEPATOCELLULAR INSUFFICIENCY. 5) TO UPDATE SECTION 4.9 OF THE SMPC TO ADD THE INFORMATION REGARDING POSSIBLE LIVER DAMAGE AND SYMPTOMS OF ACUTE RENAL FAILURE.
PL 02855/0246	PARACETAMOL, CODEINE PHOSPHATE AND CAFFEINE OMEGA 500MG/12.8/30 MG SOLUBLE TABLETS	GRANTED	PL 02855/0246-0009	PL 02855/0246-0009	30/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.6 OF THE SPC RELATING TO THE CONSUMPTION OF CAFFEINE DURING PREGNANCY FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, IMPACTING THE PIL. 2) TO UPDATE SECTION 4.4 OF THE SPC TO CORRECT STATEMENT REGARDING USE OF PARACETAMOL IN PATIENTS WITH HEPATOCELLULAR INSUFFICIENCY FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, IMPACTING THE PIL.

										3) TO UPDATE SECTIONS 4.4. 4.5 AND 4.8 OF THE SPC IN LINE WITH THE PRAC RECOMMENDATION ON PARACETAMOL ADOPTED ON 6 FEBRUARY 2014 (EMA/PRAC/65788/2014) AND CMDH RECOMMENDATIONS. CONSEQUENTLY, IMPACTING THE PIL. IN ADDITION TO THE ABOVE SAFETY CHANGES UPDATE HAVE BEEN MADE TO THE THE APPLICABLE EXCIPIENTS INFORMATION IN THE SPC AND LEAFLET, TO BE IN COMPLIANCE WITH THE REVISED ANNEX TO THE EXCIPIENT GUIDELINES (EMA/CHMP/302620/2017).
PL 02855/0246	PARACETAMOL, CODEINE PHOSPHATE AND CAFFEINE OMEGA 500MG/12.8/30 MG SOLUBLE TABLETS	GRANTED	PL 02855/0246-0009	PL 02855/0246-0009	30/09/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.6 OF THE SPC RELATING TO THE CONSUMPTION OF CAFFEINE DURING PREGNANCY FOLLOWING NEW PHARMACOVIGILANCE DATA.

										CONSEQUENTLY, IMPACTING THE PIL. 2) TO UPDATE SECTION 4.4 OF THE SPC TO CORRECT STATEMENT REGARDING USE OF PARACETAMOL IN PATIENTS WITH HEPATOCELLULAR INSUFFICIENCY FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, IMPACTING THE PIL. 3) TO UPDATE SECTIONS 4.4. 4.5 AND 4.8 OF THE SPC IN LINE WITH THE PRAC RECOMMENDATION ON PARACETAMOL ADOPTED ON 6 FEBRUARY 2014 (EMA/PRAC/65788/2014) AND CMDH RECOMMENDATIONS. CONSEQUENTLY, IMPACTING THE PIL. IN ADDITION TO THE ABOVE SAFETY CHANGES UPDATE HAVE BEEN MADE TO THE THE APPLICABLE EXCIPIENTS INFORMATION IN THE

										SPC AND LEAFLET, TO BE IN COMPLIANCE WITH THE REVISED ANNEX TO THE EXCIPIENT GUIDELINES (EMA/CHMP/302620/2017).
PL 10085/0054	ALUTARD SQ BEE 100 000 SQ U/ML, SUSPENSION FOR INJECTION	GRANTED	PL 10085/0054-0009	PL 10085/0054-0009	02/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO THE NEW TEMPLATE FORMAT AS SPECIFIED IN EMA´S GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP) MODULE V REV. 2, I.E. FROM VERSION 02 TO VERSION 2.1.
PL 10085/0055	ALUTARD SQ BEE INITIAL PACK (100 SQ U/ML, 1 000 SQ U/ML, 10 000 SQ U/ML AND 100 000 SQ U/ML), SUSPEN	GRANTED	PL 10085/0055-0009	PL 10085/0055-0009	02/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO THE NEW TEMPLATE FORMAT AS SPECIFIED IN EMA´S GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP) MODULE V REV. 2, I.E. FROM VERSION 02 TO VERSION 2.1.
PL 10085/0056	ALUTARD SQ WASP, 100 000 SQ U/ML SUSPENSION FOR INJECTION	GRANTED	PL 10085/0056-0008	PL 10085/0056-0008	02/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION NUMBER 2 TO VERSION NUMBER 2.1) IN LINE WITH EMA GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP) MODULE V REV. 2.

PL 10085/0057	ALUTARD SQ WASP, INITIAL PACK (100 SQ U/ML, 1 000 SQ U/ML, 10 000 SQ U/ML AND 100 000 SQ U/ML), SUSP	GRANTED	PL 10085/0057-0008	PL 10085/0057-0008	02/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION NUMBER 2 TO VERSION NUMBER 2.1) IN LINE WITH EMA GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP) MODULE V REV. 2.
PL 00101/0956	DIOVAN 3 MG/ML ORAL SOLUTION	GRANTED	PL 00101/0956-0067	PL 00101/0956-0067	04/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.8 ANF 5.1 OF THE SMPC AND PIL TO INCLUDE PATIENTS FROM 1 TO 5 YEARS OF AGE. TO UPDATE THE RISK MANAGEMENT PLAN(RMPV7.0) TO REFLECT COMPLETION OF STUDY K2305. ON 24 JULY 2015.
PL 00101/0956	DIOVAN 3 MG/ML ORAL SOLUTION	GRANTED	PL 00101/0956-0067	PL 00101/0956-0067	04/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.8 ANF 5.1 OF THE SMPC AND PIL TO INCLUDE PATIENTS FROM 1 TO 5 YEARS OF AGE. TO UPDATE THE RISK MANAGEMENT PLAN(RMPV7.0) TO REFLECT COMPLETION OF STUDY K2305. ON 24 JULY 2015.

PL 08828/0214	PL 08828/0214	GRANTED	PL 08828/0214-0037	PL 08828/0214-0037	07/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO INTRODUCE AN RMP FOR ROPIVACAINE KABI SOLUTION FOR INJECTION.
PL 08828/0215	ROPIVACAINE 2 MG/ML SOLUTION FOR INFUSION	GRANTED	PL 08828/0215-0038	PL 08828/0215-0038	07/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO INTRODUCE AN RMP FOR ROPIVACAINE KABI SOLUTION FOR INJECTION.
PL 08828/0217	ROPIVACAINE 7.5 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 08828/0217-0038	PL 08828/0217-0038	07/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO INTRODUCE AN RMP FOR ROPIVACAINE KABI SOLUTION FOR INJECTION.
PL 08828/0218	ROPIVACAINE 10 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 08828/0218-0038	PL 08828/0218-0038	07/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE IB ¿ CMS RMP	MUTUAL RECOGNITION	TO INTRODUCE AN RMP FOR ROPIVACAINE KABI SOLUTION FOR INJECTION.
PL 34926/0004	SOMATULINE LA 30MG, POWDER FOR SUSPENSION FOR INJECTION	GRANTED	PL 34926/0004-0019	PL 34926/0004-0019	13/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS AND PRECAUTIONS FOR USE) AND 4.8 (UNDESIRABLE EFFECTS) OF THE SPC AND CONSEQUENTIALLY THE LEAFLET BY ADDING A WARNING REGARDING COMPLICATIONS OF

										CHOLELITHIASIS AND CHOLANGITIS AS AN ADVERSE EFFECT.
PL 34926/0005	SOMATULINE AUTOGEL 60MG, SOLUTION FOR INJECTION	GRANTED	PL 34926/0005-0041	PL 34926/0005-0041	13/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS AND PRECAUTIONS FOR USE) AND 4.8 (UNDESIRABLE EFFECTS) OF THE SPC AND CONSEQUENTIALLY THE LEAFLET BY ADDING A WARNING REGARDING COMPLICATIONS OF CHOLELITHIASIS AND CHOLANGITIS AS AN ADVERSE EFFECT.
PL 34926/0006	SOMATULINE AUTOGEL 90MG, SOLUTION FOR INJECTION	GRANTED	PL 34926/0006-0039	PL 34926/0006-0039	13/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS AND PRECAUTIONS FOR USE) AND 4.8 (UNDESIRABLE EFFECTS) OF THE SPC AND CONSEQUENTIALLY THE LEAFLET BY ADDING A WARNING REGARDING COMPLICATIONS OF CHOLELITHIASIS AND CHOLANGITIS AS AN ADVERSE EFFECT.
PL 34926/0007	SOMATULINE AUTOGEL 120MG, SOLUTION FOR INJECTION	GRANTED	PL 34926/0007-0040	PL 34926/0007-0040	13/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS AND PRECAUTIONS FOR

								RD) - CMS WORKSHARING		USE) AND 4.8 (UNDESIRABLE EFFECTS) OF THE SPC AND CONSEQUENTIALLY THE LEAFLET BY ADDING A WARNING REGARDING COMPLICATIONS OF CHOLELITHIASIS AND CHOLANGITIS AS AN ADVERSE EFFECT.
PL 13689/0001	CAPD/DPCA 17 SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0001-0050	PL 13689/0001-0050	14/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 AND 4.8 OF THE SMPC AND SECTION 2 AND 4 OF PIL OF FRESENIUS MEDICAL CARE AFFECTED MEDICINAL PRODUCTS (SOLUTIONS FOR PERITONEAL DIALYSIS) IN LINE WITH THE FRAME OF ROUTINE PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIES.
PL 13689/0002	CAPD/DPCA 18 SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0002-0051	PL 13689/0002-0051	14/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 AND 4.8 OF THE SMPC AND SECTION 2 AND 4 OF PIL OF FRESENIUS MEDICAL CARE AFFECTED MEDICINAL PRODUCTS (SOLUTIONS FOR PERITONEAL DIALYSIS) IN LINE

										WITH THE FRAME OF ROUTINE PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIES.
PL 13689/0003	CAPD/DPCA 19 SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0003-0051	PL 13689/0003-0051	14/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 AND 4.8 OF THE SMPC AND SECTION 2 AND 4 OF PIL OF FRESENIUS MEDICAL CARE AFFECTED MEDICINAL PRODUCTS (SOLUTIONS FOR PERITONEAL DIALYSIS) IN LINE WITH THE FRAME OF ROUTINE PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIES.
PL 04569/1308	CEFIXIME 400MG FILM-COATED TABLETS	GRANTED	PL 04569/1308-0017	PL 04569/1308-0017	17/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.3 OF THE SMPC AND SECTION 3 OF THE PIL FOLLOWING ASSESSMENT OF THE SAME CHANGES FOR THE REFERENCE PRODUCT SUPRAX 200MG TABLETS (SANOFI) WHICH IS REGISTERED NATIONALLY.
PL 21597/0005	EPIVAL CR 300MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21597/0005-0031	PL 21597/0005-0031	18/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO INTRODUCE A RISK MANAGEMENT PLAN UPON COMMISSION DECISION TO REFERRAL EMEA/H/A-

								RD) - CMS		31/1454 FOR MEDICINAL PRODUCTS CONTAINING SUBSTANCES RELATED TO VALPROATE.
PL 21597/0006	EPIVAL CR 500MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21597/0006-0030	PL 21597/0006-0030	18/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE A RISK MANAGEMENT PLAN UPON COMMISSION DECISION TO REFERRAL EMEA/H/A-31/1454 FOR MEDICINAL PRODUCTS CONTAINING SUBSTANCES RELATED TO VALPROATE.
PL 15513/0342	IMODIUM PLUS CAPLET	GRANTED	PL 15513/0342-0073	PL 15513/0342-0073	23/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4.4 AND 4.9 IN LINE WITH PRAC WORDING REGARDING BRUGADA SYNDROME.
PL 00025/0357	SINGULAIR PAEDIATRIC 5MG CHEWABLE TABLETS	GRANTED	PL 00025/0357-0100	PL 00025/0357-0100	24/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	(1) TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE CCDS BY ADDING THE SIDE-EFFECT OBSESSIVE-COMPULSIVE SYMPTOMS. (2) TO UPDATE SECTION 2 OF THE SMPC WITH THE ADDITION OF THE EXCIPIENT WARNING

										FOR SODIUM IN LINE WITH THE EXCIPIENTS GUIDELINES. CONSEQUENTLY, THE PRODUCT INFORMATION LEAFLET HAS BEEN UPDATED.
PL 00025/0357	SINGULAIR PAEDIATRIC 5MG CHEWABLE TABLETS	GRANTED	PL 00025/0357-0100	PL 00025/0357-0100	24/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	(1) TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE CCDS BY ADDING THE SIDE-EFFECT OBSESSIVE-COMPULSIVE SYMPTOMS. (2) TO UPDATE SECTION 2 OF THE SMPC WITH THE ADDITION OF THE EXCIPIENT WARNING FOR SODIUM IN LINE WITH THE EXCIPIENTS GUIDELINES. CONSEQUENTLY, THE PRODUCT INFORMATION LEAFLET HAS BEEN UPDATED.
PL 00025/0358	SINGULAIR 10MG FILM-COATED TABLET	GRANTED	PL 00025/0358-0096	PL 00025/0358-0096	24/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	(1) TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE CCDS BY ADDING THE SIDE-EFFECT OBSESSIVE-COMPULSIVE

								WORKSHARING		SYMPTOMS. (2) TO UPDATE SECTION 2 OF THE SMPC WITH THE ADDITION OF THE EXCIPIENT WARNING FOR SODIUM IN LINE WITH THE EXCIPIENTS GUIDELINES. CONSEQUENTLY, THE PRODUCT INFORMATION LEAFLET HAS BEEN UPDATED.
PL 00025/0358	SINGULAIR 10MG FILM-COATED TABLET	GRANTED	PL 00025/0358-0096	PL 00025/0358-0096	24/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	(1) TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE CCDS BY ADDING THE SIDE-EFFECT OBSESSIVE-COMPULSIVE SYMPTOMS. (2) TO UPDATE SECTION 2 OF THE SMPC WITH THE ADDITION OF THE EXCIPIENT WARNING FOR SODIUM IN LINE WITH THE EXCIPIENTS GUIDELINES. CONSEQUENTLY, THE PRODUCT INFORMATION LEAFLET HAS BEEN UPDATED.

PL 00025/0412	SINGULAIR PAEDIATRIC 4MG CHEWABLE TABLETS	GRANTED	PL 00025/0412-0091	PL 00025/0412-0091	24/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	(1) TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE CCDS BY ADDING THE SIDE-EFFECT OBSESSIVE-COMPULSIVE SYMPTOMS. (2) TO UPDATE SECTION 2 OF THE SMPC WITH THE ADDITION OF THE EXCIPIENT WARNING FOR SODIUM IN LINE WITH THE EXCIPIENTS GUIDELINES. CONSEQUENTLY, THE PRODUCT INFORMATION LEAFLET HAS BEEN UPDATED.
PL 00025/0412	SINGULAIR PAEDIATRIC 4MG CHEWABLE TABLETS	GRANTED	PL 00025/0412-0091	PL 00025/0412-0091	24/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	(1) TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE CCDS BY ADDING THE SIDE-EFFECT OBSESSIVE-COMPULSIVE SYMPTOMS. (2) TO UPDATE SECTION 2 OF THE SMPC WITH THE ADDITION OF THE EXCIPIENT WARNING FOR SODIUM IN LINE WITH THE EXCIPIENTS

										GUIDELINES. CONSEQUENTLY, THE PRODUCT INFORMATION LEAFLET HAS BEEN UPDATED.
PL 00025/0440	SINGULAIR PAEDIATRIC 4MG GRANULES	GRANTED	PL 00025/0440-0095	PL 00025/0440-0095	24/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	(1) TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE CCDS BY ADDING THE SIDE-EFFECT OBSESSIVE-COMPULSIVE SYMPTOMS. (2) TO UPDATE SECTION 2 OF THE SMPC WITH THE ADDITION OF THE EXCIPIENT WARNING FOR SODIUM IN LINE WITH THE EXCIPIENTS GUIDELINES. CONSEQUENTLY, THE PRODUCT INFORMATION LEAFLET HAS BEEN UPDATED.
PL 00025/0440	SINGULAIR PAEDIATRIC 4MG GRANULES	GRANTED	PL 00025/0440-0095	PL 00025/0440-0095	24/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	(1) TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE CCDS BY ADDING THE SIDE-EFFECT OBSESSIVE-COMPULSIVE SYMPTOMS.

										(2) TO UPDATE SECTION 2 OF THE SMPC WITH THE ADDITION OF THE EXCIPIENT WARNING FOR SODIUM IN LINE WITH THE EXCIPIENTS GUIDELINES. CONSEQUENTLY, THE PRODUCT INFORMATION LEAFLET HAS BEEN UPDATED.
PL 17780/0306	LOPRAZOLAM 1MG TABLETS	GRANTED	PL 17780/0306-0048	PL 17780/0306-0048	24/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SPC ACCORDING TO ARTICLE 20 OF COMMISSION REGULATION (EC) NO 1234/2008 TO TO ACHIEVE AN HARMONISED UPDATE OF THE ¿PREGNANCY -RELATED¿ SECTIONS IN THE PRODUCT INFORMATION IN ALL EU MEMBER STATES. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 18017/0006	DICLOFENAC SODIUM SPRAY GEL 4% W/W CUTANEOUS SPRAY, SOLUTION	GRANTED	PL 18017/0006-0013	PL 18017/0006-0013	25/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-2, 4-3, 4-4, 4-8, 5-1, 6-1, LABEL AND PIL FOLLOWING A REPEAT-USE PROCEDURE (WITH CHANGE OF RMS),

										PLUS QRD AND FMD CHANGES.
PL 45496/0009	BELKYRA 10 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 45496/0009-0008	PL 45496/0009-0008	25/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO SUBMIT AN UPDATED RISK MANAGEMENT PLAN (RMP) V6.0 AS PER PRAC RECOMMENDATION FOLLOWING PSUSA ASSESSMENT REPORT ON DEOXYCHOLIC ACID, PROCEDURE NO.: PSUSA/00010525/201804, RECEIVED ON 29 NOVEMBER 2018.
PL 00101/1007	TOBRADEX 3MG/ML/1MG/ML EYE DROPS, SUSPENSION	GRANTED	PL 00101/1007-0011	PL 00101/1007-0011	28/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SECTION 4.4 WARNINGS AND PRECAUTIONS OF THE SUMMARY OF PRODUCT CHARACTERISTICS AND SECTION 4 OF THE PATIENT LEAFLET IN LINE THE WITH LATEST CORE DATA SHEET.
PL 17770/0001	ZIBOR 2,500 IU ANTI-XA/0.2 ML SOLUTION FOR INJECTION	GRANTED	PL 17770/0001-0021	PL 17770/0001-0021	28/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 (FERTILITY, PREGNANCY AND LACTATION) OF THE SPC BASED ON THE MOST RECENT SCIENTIFIC EVIDENCES OF BEMIPARIN AND OTHER LMWH AND

										RECOMMENDATIONS FROM INTERNATIONAL GUIDELINES AS WELL AS THE RESULTS OF THE PHASE 1 CLINICAL TRIAL ROV-BEM-2008-01 (NCT00863577/N EUDRACT: 2008-006267-36) TO EVALUATE THE TOLERABILITY AND PHARMACOKINETICS OF BEMIPARIN IN TABLETS.
PL 17770/0002	ZIBOR 3,500 IU ANTI-XA/0.2ML SOLUTION FOR INJECTION	GRANTED	PL 17770/0002-0022	PL 17770/0002-0022	28/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 (FERTILITY, PREGNANCY AND LACTATION) OF THE SPC BASED ON THE MOST RECENT SCIENTIFIC EVIDENCES OF BEMIPARIN AND OTHER LMWH AND RECOMMENDATIONS FROM INTERNATIONAL GUIDELINES AS WELL AS THE RESULTS OF THE PHASE 1 CLINICAL TRIAL ROV-BEM-2008-01 (NCT00863577/N EUDRACT: 2008-006267-36) TO EVALUATE THE TOLERABILITY AND PHARMACOKINETICS OF BEMIPARIN IN TABLETS.

PL 17770/0003	ZIBOR 25,000 IU ANTI-XA/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGES	GRANTED	PL 17770/0003-0019	PL 17770/0003-0019	28/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 (FERTILITY, PREGNANCY AND LACTATION) OF THE SPC BASED ON THE MOST RECENT SCIENTIFIC EVIDENCES OF BEMIPARIN AND OTHER LMWH AND RECOMMENDATIONS FROM INTERNATIONAL GUIDELINES AS WELL AS THE RESULTS OF THE PHASE 1 CLINICAL TRIAL ROV-BEM-2008-01 (NCT00863577/N EUDRACT: 2008-006267-36) TO EVALUATE THE TOLERABILITY AND PHARMACOKINETICS OF BEMIPARIN IN TABLETS.
PL 49452/0001	SOLACUTAN 3% GEL	GRANTED	PL 49452/0001-0006	PL 49452/0001-0006	28/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 2-0, 4-1, 4-2, 4-4, 4-8, 5-1 AND PIL IN LINE WITH THE REFERENCE PRODUCT SOLARAZE 3% GEL (ALMIRALL S.A.), WITH THE QRD TEMPLATE AND THE EXCIPIENTS GUIDELINE.
PL 11896/0025	LISINOPRIL/HYDROCHLOROTHIAZIDE, 10 MG/12.5 MG TABLETS	GRANTED	PL 11896/0025-0023	PL 11896/0025-0023	30/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3,4.4 AND 4.5 OF THE SMPC FOLLOWING AN INTERNAL

								RD) - CMS		PHARMACOVIGILANCE SIGNAL ON DRUG INTERACTION OF GENERIC ACE INHIBITORS AND NEPRILYS INHIBITORS RESULTING IN AN INCREASED RISK OF ANGIOEDEMA. THE SMPC HAS ALSO BEEN UPDATED IN LINE WITH PSUSA/00000749/201802. CONSEQUENTLY CHANGES HAVE BEEN MADE TO THE PIL.
PL 11896/0026	LISINOPRIL/HYDROCHLOROTHIAZIDE, 20 MG/12.5 MG TABLETS	GRANTED	PL 11896/0026-0023	PL 11896/0026-0023	30/10/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3,4.4 AND 4.5 OF THE SMPC FOLLOWING AN INTERNAL PHARMACOVIGILANCE SIGNAL ON DRUG INTERACTION OF GENERIC ACE INHIBITORS AND NEPRILYS INHIBITORS RESULTING IN AN INCREASED RISK OF ANGIOEDEMA. THE SMPC HAS ALSO BEEN UPDATED IN LINE WITH PSUSA/00000749/201802. CONSEQUENTLY CHANGES HAVE BEEN MADE TO THE PIL.
PL 04425/0199	DEPAKOTE 250MG TABLETS	GRANTED	PL 04425/0	PL 04425/0	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE

			199-0087	199-0087				(STANDARD) - CMS WORKSHARING		CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0200	DEPAKOTE 500MG TABLETS	GRANTED	PL 04425/0200-0092	PL 04425/0200-0092	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 04425/0300	EPILIM LIQUID 200MG/5ML	GRANTED	PL 04425/0300-0067	PL 04425/0300-0067	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0301	EPILIM SYRUP 200MG/5ML	GRANTED	PL 04425/0301-0075	PL 04425/0301-0075	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE

										PIL HAS BEEN UPDATED.
PL 04425/0302	EPILIM 200 GASTRO-RESISTANT TABLETS	GRANTED	PL 04425/0302-0082	PL 04425/0302-0082	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0303	EPILIM 500 GASTRO-RESISTANT TABLETS	GRANTED	PL 04425/0303-0079	PL 04425/0303-0079	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED

										SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0307	EPILIM CHRONO 200MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0307-0084	PL 04425/0307-0084	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0308	EPILIM CHRONO 300MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0308-0091	PL 04425/0308-0091	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED

										SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0309	EPILIM CHRONO 500MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0309-0086	PL 04425/0309-0086	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0310	EPILIM CHRONOSPHERE MR 50 MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0310-0088	PL 04425/0310-0088	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND

										RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0312	EPILIM CHRONOSPHERE MR 100MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0312-0091	PL 04425/0312-0091	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0313	EPILIM CHRONOSPHERE MR 250MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0313-0089	PL 04425/0313-0089	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING

										VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0314	EPILIM CHRONOSPHERE MR 500MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0314-0091	PL 04425/0314-0091	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0315	EPILIM CHRONOSPHERE MR 750MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0315-0089	PL 04425/0315-0089	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER'

										CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0316	EPILIM CHRONOSPHERE MR 1000MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0316-0087	PL 04425/0316-0087	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0317	EPILIM 100MG CRUSHABLE TABLETS	GRANTED	PL 04425/0317-0071	PL 04425/0317-0071	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL

										TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0685	EPILIM 400MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 04425/0685-0056	PL 04425/0685-0056	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.2 OF THE SMPC, TO INCLUDE CLINICAL INFORMATION ON 'TERATOGENICITY AND DEVELOPMENTAL EFFECTS AND CONGENITAL MALFORMATIONS' AND 'PLACENTAL TRANSFER' CONCERNING VALPROATE AND RELATED SUBSTANCES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04569/0549	OFLOXACIN 200MG TABLETS	GRANTED	PL 04569/0549-0048	PL 04569/0549-0048	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.1, 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3 AND 6.1 OF THE SMPC, LABELLING AND PIL IN LINE WITH THE REFERENCE PRODUCT TARIVID 400 MG FILM-COATED TABLETS, PL

										04425/0217 FROM SANOFI-AVENTIS AND TO UPDATE THE PRODUCT INFORMATION IN LINE WITH THE LATEST QRD TEMPLATE AND SOME EDITORIAL CHANGES.
PL 04569/0550	OFLOXACIN 400MG TABLETS	GRANTED	PL 04569/0550-0056	PL 04569/0550-0056	01/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.1, 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3 AND 6.1 OF THE SMPC, LABELLING AND PIL IN LINE WITH THE REFERENCE PRODUCT TARIVID 400 MG FILM-COATED TABLETS, PL 04425/0217 FROM SANOFI-AVENTIS AND TO UPDATE THE PRODUCT INFORMATION IN LINE WITH THE LATEST QRD TEMPLATE AND SOME EDITORIAL CHANGES.
PL 04416/0856	LECADO 100/25 MG MODIFIED-RELEASE TABLETS	GRANTED	PL 04416/0856-0032	PL 04416/0856-0032	05/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 6.5 AND 6.6 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT AND WITH THE LATEST QRD TEMPLATE. CONSEQUENTIALLY

										THE LABEL AND PIL HAS BEEN UPDATED.
PL 04416/0857	LECADO 200/50 MG MODIFIED RELEASE TABLETS	GRANTED	PL 04416/0857-0030	PL 04416/0857-0030	05/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 6.5 AND 6.6 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT AND WITH THE LATEST QRD TEMPLATE. CONSEQUENTIALLY THE LABEL AND PIL HAS BEEN UPDATED.
PL 10414/0001	LIQUID MEDICAL OXYGEN 100% MEDICINAL GAS, CRYOGENIC	GRANTED	PL 10414/0001-0015	PL 10414/0001-0015	11/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5, 4-6, 4-7, 4-8, 4-9 AND PIL IN LINE WITH THE CCDS.
PL 10414/0002	MEDICAL OXYGEN 100% MEDICINAL GAS, COMPRESSED	GRANTED	PL 10414/0002-0015	PL 10414/0002-0015	11/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5, 4-6, 4-7, 4-8, 4-9 AND PIL IN LINE WITH THE CCDS.
PL 35326/0006	LIQUID MEDICAL OXYGEN 100% MEDICINAL GAS, CRYOGENIC	GRANTED	PL 35326/0006-0025	PL 35326/0006-0025	11/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5, 4-6, 4-7, 4-8, 4-9 AND PIL IN LINE WITH THE CCDS.

PL 35326/0007	LIQUID MEDICAL OXYGEN 100% MEDICINAL GAS, CRYOGENIC	GRANTED	PL 35326/0007-0027	PL 35326/0007-0027	11/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5, 4-6, 4-7, 4-8, 4-9 AND PIL IN LINE WITH THE CCDS.
PL 35326/0008	MEDICAL OXYGEN 100% MEDICINAL GAS, COMPRESSED	GRANTED	PL 35326/0008-0030	PL 35326/0008-0030	11/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5, 4-6, 4-7, 4-8, 4-9 AND PIL IN LINE WITH THE CCDS.
PL 15513/0378	BENADRYL ALLERGY LIQUID RELEASE 10MG CAPSULES	GRANTED	PL 15513/0378-0030	PL 15513/0378-0030	12/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 2-0, 4-4, 4-6, 4-7, 4-8, LABEL AND PIL IN LINE WITH THE REFERENCE PRODUCT ZIRTEK TABLETS, AND WITH THE CCDS. FORMATTING, EDITORIAL AND EXCIPIENT GUIDELINE CHANGES HAVE ALSO BEEN MADE.
PL 15513/0378	BENADRYL ALLERGY LIQUID RELEASE 10MG CAPSULES	GRANTED	PL 15513/0378-0030	PL 15513/0378-0030	12/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 2-0, 4-4, 4-6, 4-7, 4-8, LABEL AND PIL IN LINE WITH THE REFERENCE PRODUCT ZIRTEK TABLETS, AND WITH THE CCDS. FORMATTING, EDITORIAL AND

										EXCIPIENT GUIDELINE CHANGES HAVE ALSO BEEN MADE.
PL 10673/0038	WILATE 500/WILATE 1000, POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 10673/0038-0049	PL 10673/0038-0049	13/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) WILATE 500/WILATE 1000, POWDER AND SOLVENT FOR SOLUTION FOR INJECTION FROM VERSION 08 TO VERSION 09.
PL 00242/0301	TOPAMAX 25 MG FILM-COATED TABLETS	GRANTED	PL 00242/0301-0148	PL 00242/0301-0148	14/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 AND 4.8 OF THE SPC TO ADD NEPHROCALCINOSIS AS ADVERSE DRUG REACTION IN LINE WITH THE REVIEW OF THE COMPANY GLOBAL SAFETY DATABASE AND REVIEW OF LITERATURE. 2) TO UPDATE SECTION 4.9 OF THE SPC TO REMOVE GASTRIC LAVAGE AND ACTIVATED CHARCOAL STATEMENTS. IN ADDITION, SOME EDITORIAL CHANGES WERE MADE TO THE LABEL AS PROPOSED BY THE RMS.

PL 00242/0302	TOPAMAX 50 MG FILM-COATED TABLETS	GRANTED	PL 00242/0302-0149	PL 00242/0302-0149	14/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 AND 4.8 OF THE SPC TO ADD NEPHROCALCINOSIS AS ADVERSE DRUG REACTION IN LINE WITH THE REVIEW OF THE COMPANY GLOBAL SAFETY DATABASE AND REVIEW OF LITERATURE. 2) TO UPDATE SECTION 4.9 OF THE SPC TO REMOVE GASTRIC LAVAGE AND ACTIVATED CHARCOAL STATEMENTS. IN ADDITION, SOME EDITORIAL CHANGES WERE MADE TO THE LABEL AS PROPOSED BY THE RMS.
PL 00242/0303	TOPAMAX 100 MG FILM-COATED TABLETS	GRANTED	PL 00242/0303-0150	PL 00242/0303-0150	14/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 AND 4.8 OF THE SPC TO ADD NEPHROCALCINOSIS AS ADVERSE DRUG REACTION IN LINE WITH THE REVIEW OF THE COMPANY GLOBAL SAFETY DATABASE AND REVIEW OF LITERATURE.

										2) TO UPDATE SECTION 4.9 OF THE SPC TO REMOVE GASTRIC LAVAGE AND ACTIVATED CHARCOAL STATEMENTS. IN ADDITION, SOME EDITORIAL CHANGES WERE MADE TO THE LABEL AS PROPOSED BY THE RMS.
PL 00242/0304	TOPAMAX 200 MG FILM-COATED TABLETS	GRANTED	PL 00242/0304-0148	PL 00242/0304-0148	14/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 AND 4.8 OF THE SPC TO ADD NEPHROCALCINOSIS AS ADVERSE DRUG REACTION IN LINE WITH THE REVIEW OF THE COMPANY GLOBAL SAFETY DATABASE AND REVIEW OF LITERATURE. 2) TO UPDATE SECTION 4.9 OF THE SPC TO REMOVE GASTRIC LAVAGE AND ACTIVATED CHARCOAL STATEMENTS. IN ADDITION, SOME EDITORIAL CHANGES WERE MADE TO THE LABEL AS PROPOSED BY THE RMS.

PL 00242/0348	TOPAMAX SPRINKLE 15 MG HARD CAPSULES	GRANTED	PL 00242/0348-0127	PL 00242/0348-0127	14/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 AND 4.8 OF THE SPC TO ADD NEPHROCALCINOSIS AS ADVERSE DRUG REACTION IN LINE WITH THE REVIEW OF THE COMPANY GLOBAL SAFETY DATABASE AND REVIEW OF LITERATURE. 2) TO UPDATE SECTION 4.9 OF THE SPC TO REMOVE GASTRIC LAVAGE AND ACTIVATED CHARCOAL STATEMENTS. IN ADDITION, SOME EDITORIAL CHANGES WERE MADE TO THE LABEL AS PROPOSED BY THE RMS.
PL 00242/0349	TOPAMAX SPRINKLE 25 MG HARD CAPSULES	GRANTED	PL 00242/0349-0129	PL 00242/0349-0129	14/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 AND 4.8 OF THE SPC TO ADD NEPHROCALCINOSIS AS ADVERSE DRUG REACTION IN LINE WITH THE REVIEW OF THE COMPANY GLOBAL SAFETY DATABASE AND REVIEW OF LITERATURE.

										2) TO UPDATE SECTION 4.9 OF THE SPC TO REMOVE GASTRIC LAVAGE AND ACTIVATED CHARCOAL STATEMENTS. IN ADDITION, SOME EDITORIAL CHANGES WERE MADE TO THE LABEL AS PROPOSED BY THE RMS.
PL 00242/0350	TOPAMAX SPRINKLE 50 MG HARD CAPSULES	GRANTED	PL 00242/0350-0127	PL 00242/0350-0127	14/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.4 AND 4.8 OF THE SPC TO ADD NEPHROCALCINOSIS AS ADVERSE DRUG REACTION IN LINE WITH THE REVIEW OF THE COMPANY GLOBAL SAFETY DATABASE AND REVIEW OF LITERATURE. 2) TO UPDATE SECTION 4.9 OF THE SPC TO REMOVE GASTRIC LAVAGE AND ACTIVATED CHARCOAL STATEMENTS. IN ADDITION, SOME EDITORIAL CHANGES WERE MADE TO THE LABEL AS PROPOSED BY THE RMS.

PL 04569/0983	EPIRUBICIN 2 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 04569/0983-0040	PL 04569/0983-0040	14/11/2019	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., 4.9, 5.1, 5.2 AND 5.3 OF THE SMPC AND PIL IN LINE WITH REFERENCE PRODUCT PHARMORUBICIN 2 MG/ML SOLUTION FOR INJECTION FROM PFIZER APS. ADDITIONALLY THE PRODUCT INFORMATION HAS BEEN UPDATED IN LINE WITH THE LATEST CMDH QRD TEMPLATE FOR MR/DC PROCEDURES (REF: CMDH/201/2005/REV.09, DATED FEBRUARY 2016) AND IN LINE WITH THE GUIDELINE ¿EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE¿ (REVISION 2, DATED ON MARCH 2018).
PL 14434/0029	NORADRENALINE (NOREPINEPHRINE) 0.08 MG/ML, SOLUTION FOR INFUSION	GRANTED	PL 14434/0029-0013	PL 14434/0029-0013	14/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.8, 6.1, 6.5 AND 6.6 OF THE SMPC, LABELLING AND PACKAGE LEAFLET (PIL)) OF THE CONCERNED MEDICINAL PRODUCT

										IN LINE WITH NEW AVAILABLE DATA.
PL 45496/0009	BELKYRA 10 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 45496/0009-0009	PL 45496/0009-0009	14/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS) V4.0 UPDATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 14598/0093	STRIVERDI RESPIMAT 2.5 MICROGRAM, INHALATION SOLUTION	GRANTED	PL 14598/0093-0031	PL 14598/0093-0031	18/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP (VERSION 3.0) FOR OLODATEROL (STRIVERDI RESPIMAT® 2.5 MICROGRAM, INHALATION SOLUTION).
PL 20416/0667	AMBELINA 0.15 MG / 0.03 MG FILM-COATED TABLETS	GRANTED	PL 20416/0667-0003	PL 20416/0667-0003	18/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1(NAME OF THE MEDICINAL PRODUCT), 2 (QUALITATIVE AND QUANTITATIVE COMPOSITION), 4.3 (CONTRAINDICATIONS), 4.5 (INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION), 4.8 (UNDESIRABLE EFFECTS), 5.2 (PHARMACOKINETIC PROPERTIES) AND 6.1 (LIST OF EXCIPIENTS) OF THE SPC AND

										CONSEQUENTIALLY THE LEAFLET IN LINE WITH THE ISSUES RAISED DURING THE INITIAL APPROVAL.
PL 31750/0043	BUPRENORPHINE 2 MG SUBLINGUAL TABLETS	GRANTED	PL 31750/0043-0030	PL 31750/0043-0030	20/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-5, 4-8 AND PIL IN LINE WITH THE REFERENCE PRODUCT SUBUTEX (INDIVIOR UK LIMITED).
PL 31750/0044	BUPRENORPHINE 8 MG SUBLINGUAL TABLETS	GRANTED	PL 31750/0044-0031	PL 31750/0044-0031	20/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-5, 4-8 AND PIL IN LINE WITH THE REFERENCE PRODUCT SUBUTEX (INDIVIOR UK LIMITED).
PL 04500/0006	HEPATECT CP 50 IU/ML SOLUTION FOR INFUSION	GRANTED	PL 04500/0006-0048	PL 04500/0006-0048	22/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.6, 4.8 AND 4.9 OF THE SPC IN LINE WITH HE "GUIDELINE ON CORE SMPC FOR HUMAN NORMAL IMMUNOGLOBULIN FOR INTRAVENOUS ADMINISTRATION (IVIG)" (EMA/CHMP/BPWP/94038/2007 REV.5). CONSEQUENTLY, IMPACTING THE PIL.
PL 11587/0090	MITOMYCIN 40 MG POWDER AND SOLVENT FOR INTRAVESICAL SOLUTION	GRANTED	PL 11587/0090-0018	PL 11587/0090-0018	23/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 2, , 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 7,8 OF THE SMPC AND PIL TO REVISE AND ADOPT FOR BETTER

										COMPLIANCE IN PATIENTS AND HEALTHCARE PROFESSIONALS AS WELL AS FOR A BETTER PATIENT SAFETY. THE UPDATE HAS BEEN MADE TTHROUGHOUT THE PRODUCT INFORMATION ACCORDING TO CMDH ANNOTATED QRD TEMPLATE FOR MR/DC PROCEDURES, VERSION 4.0 AND QRD CONVENTION TO BE FOLLOWED FOR THE EMA-QRD TEMPLATES, EMA/62470/2007 REV. 8.
PL 44124/0004	HEPARIN 5,000 I.U./ML, SOLUTION FOR INJECTION	GRANTED	PL 44124/0004-0019	PL 44124/0004-0019	28/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.5 AND 4.8 OF THE SMPC AND PIL 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 HAS ALSO BEEN DONE.
PL 00049/0042	DURAPHAT 50 MG/ML DENTAL SUSPENSION	GRANTED	PL 00049/0042-0068	PL 00049/0042-0068	29/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC 4-8 TO ADD "HYPERSENSITIVITY REACTION", WITH A CONSEQUENTIAL UPDATE TO THE PIL.
PL 44124/0017	CEFTRIAXONE 500 MG POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 44124/0017-0005	PL 44124/0017-0005	29/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL IN LINE WITH THE PRAC ASSESSMENT REPORT ON THE PSUR(S) FOR CEFTRIAXONE 500 MG, 1 MG, 2, MG POWDER FOR SOLUTION FOR INJECTION AND SECTION 4.8 HAS BEEN UPDATED TO HE RISK OF HEPATITIS IN LINE WITH COMPANY CORE DATA SHEET. ADDITIONALLY THE NATIONAL TEXT HAS BEEN UPDATED IN LINE WITH QRD TEMPLATE. THE LEAFLET MOCK-UP SHOULD BE

										SUBMITTED AT THE NEXT REGULATORY UPDATE.
PL 44124/0017	CEFTRIAXONE 500 MG POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 44124/0017-0005	PL 44124/0017-0005	29/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL IN LINE WITH THE PRAC ASSESSMENT REPORT ON THE PSUR(S) FOR CEFTRIAXONE 500 MG, 1 MG, 2, MG POWDER FOR SOLUTION FOR INJECTION AND SECTION 4.8 HAS BEEN UPDATED TO HE RISK OF HEPATITIS IN LINE WITH COMPANY CORE DATA SHEET. ADDITIONALLY THE NATIONAL TEXT HAS BEEN UPDATED IN LINE WITH QRD TEMPLATE. THE LEAFLET MOCK-UP SHOULD BE SUBMITTED AT THE NEXT REGULATORY UPDATE.
PL 44124/0018	CEFTRIAXONE 1G POWDER FOR SOLUTION FOR INJECTION /INFUSION	GRANTED	PL 44124/0018-0005	PL 44124/0018-0005	29/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL IN LINE WITH THE PRAC ASSESSMENT REPORT ON THE PSUR(S) FOR CEFTRIAXONE 500 MG, 1 MG, 2, MG POWDER

										FOR SOLUTION FOR INJECTION AND SECTION 4.8 HAS BEEN UPDATED TO HE RISK OF HEPATITIS IN LINE WITH COMPANY CORE DATA SHEET. ADDITIONALLY THE NATIONAL TEXT HAS BEEN UPDATED IN LINE WITH QRD TEMPLATE. THE LEAFLET MOCK-UP SHOULD BE SUBMITTED AT THE NEXT REGULATORY UPDATE.
PL 44124/0018	CEFTRIAXONE 1G POWDER FOR SOLUTION FOR INJECTION /INFUSION	GRANTED	PL 44124/0018-0005	PL 44124/0018-0005	29/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL IN LINE WITH THE PRAC ASSESSMENT REPORT ON THE PSUR(S) FOR CEFTRIAXONE 500 MG, 1 MG, 2, MG POWDER FOR SOLUTION FOR INJECTION AND SECTION 4.8 HAS BEEN UPDATED TO HE RISK OF HEPATITIS IN LINE WITH COMPANY CORE DATA SHEET. ADDITIONALLY THE NATIONAL TEXT HAS BEEN UPDATED IN LINE WITH QRD

										TEMPLATE. THE LEAFLET MOCK-UP SHOULD BE SUBMITTED AT THE NEXT REGULATORY UPDATE.
PL 44124/0019	CEFTRIAXONE 2G POWDER FOR SOLUTION FOR INJECTION /INFUSION	GRANTED	PL 44124/0019-0005	PL 44124/0019-0005	29/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL IN LINE WITH THE PRAC ASSESSMENT REPORT ON THE PSUR(S) FOR CEFTRIAXONE 500 MG, 1 MG, 2, MG POWDER FOR SOLUTION FOR INJECTION AND SECTION 4.8 HAS BEEN UPDATED TO HE RISK OF HEPATITIS IN LINE WITH COMPANY CORE DATA SHEET. ADDITIONALLY THE NATIONAL TEXT HAS BEEN UPDATED IN LINE WITH QRD TEMPLATE. THE LEAFLET MOCK-UP SHOULD BE SUBMITTED AT THE NEXT REGULATORY UPDATE.

PL 44124/0019	CEFTRIAXONE 2G POWDER FOR SOLUTION FOR INJECTION /INFUSION	GRANTED	PL 44124/0019-0005	PL 44124/0019-0005	29/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL IN LINE WITH THE PRAC ASSESSMENT REPORT ON THE PSUR(S) FOR CEFTRIAXONE 500 MG, 1 MG, 2, MG POWDER FOR SOLUTION FOR INJECTION AND SECTION 4.8 HAS BEEN UPDATED TO HE RISK OF HEPATITIS IN LINE WITH COMPANY CORE DATA SHEET. ADDITIONALLY THE NATIONAL TEXT HAS BEEN UPDATED IN LINE WITH QRD TEMPLATE. THE LEAFLET MOCK-UP SHOULD BE SUBMITTED AT THE NEXT REGULATORY UPDATE.
PL 04854/0158	LEVOSERT 20 MICROGRAM/24 HOURS INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 04854/0158-0027	PL 04854/0158-0027	29/11/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE RMP (FROM VERSION 8.2 TO VERSION 8.3) FOR LEVOSERT 20 MICROGRAM/24 HOURS INTRAUTERINE DELIVERY SYSTEM IN ACCORDANCE WITH THE GUIDELINE ON GOOD PHARMACOVIGILANCE

										PRACTICES (GVP) MODULE V (EMA/838713/2011 REV 2).
PL 04515/0159	PACLITAXEL 6MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 04515/0159-0083	PL 04515/0159-0083	30/11/2019	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 1)THE REVIEW OF AVAILABLE SAFETY INFORMATION FOR PACLITAXEL AND THE UPDATE OF THE COMPANIES CORE SAFETY INFORMATION THE MAH. 2) ADDITIONALLY AT THE REQUEST OF THE IRISH AUTHORITY SECTION 6.6 IS BEING UPDATED. THE PIL MOCK UP HAS TEMPORARILY BEEN REPLACED BY TEXT, AWAITING THE NATIONAL ARTICLE 61(3) SUBMISSION.
PL 00010/0514	RENNIE EXTRA TABLETS	GRANTED	PL 00010/0514-0049	PL 00010/0514-0049	02/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	- TO UPDATE SECTIONS 4.2, 4.5, 4.6, 4.8, 5.3 AND 6.6 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET (VERSION 4.0) FOR RENNIE DUAL ACTION CHEWABLE TABLETS. - TO UPDATE THE SODIUM AND

										GLUCOSE/SUCROSE WARNING IN THE PACKAGE LEAFLET AND THE ADDITION OF A WARNING RELATED TO SODIUM AND GLUCOSE/SUCROSE IN THE SUMMARY OF PRODUCT CHARACTERISTICS (SECTION 4.4) AS A RESULT OF THE EUROPEAN COMMISSION'S UPDATED GUIDELINE. - IN ADDITION, UPDATES TO THE PRODUCT INFORMATION WERE MADE IN LINE WITH THE LATEST QRD TEMPLATE AND THE LABELLING HAVE BEEN UPDATED TO STATE THAT THE UNIQUE IDENTIFIER AND 2D CODE ARE NOT APPLICABLE FOR THIS PRODUCT. - TO UPDATE THE MEDICINAL PRODUCT NAME IN THE SMPC (SECTION 1), LABELLING AND PACKAGE LEAFLET TO REFLECT THE NAME

										APPROVED IN THE NEW RMS, IRELAND.
PL 46796/0001	BCG VACCINE AJV, POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION.	GRANTED	PL 46796/0001-0017	PL 46796/0001-0017	05/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) TO FULFIL THE LEGISLATIVE REQUIREMENTS FOR THE RMP TO BE IN ACCORDANCE WITH GOOD PHARMACOVIGILANCE PRACTICE (GVP) MODULE V, REVISION 2.
PL 46796/0002	DILUTED SAUTON AJV	GRANTED	PL 46796/0002-0015	PL 46796/0002-0015	05/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) TO FULFIL THE LEGISLATIVE REQUIREMENTS FOR THE RMP TO BE IN ACCORDANCE WITH GOOD PHARMACOVIGILANCE PRACTICE (GVP) MODULE V, REVISION 2.
PL 04425/0170	SABRIL SACHET 0.5G	GRANTED	PL 04425/0170-0063	PL 04425/0170-0063	05/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC TO ADD INFORMATION REGARDING TUNNEL VISION, VISUAL ACUITY AND RETINAL DISORDER. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 04425/0171	SABRIL TABLETS 500MG	GRANTED	PL 04425/0171-0065	PL 04425/0171-0065	05/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC TO ADD INFORMATION REGARDING TUNNEL VISION, VISUAL ACUITY AND RETINAL DISORDER. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 13689/0021	BICAVERA 1.5 % GLUCOSE, 1.25 MMOL/L CALCIUM, SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0021-0006	PL 13689/0021-0006	06/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO EPS IN AN APPROPRIATE MANNER FOLLOWING PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIE. CONSEQUENTLY, IMPACTING THE PIL. THE LEAFLET HAS NOT BEEN APPROVED WITH THIS VARIATION AS THE CURRENTLY APPROVED LEAFLET ALREADY INCLUDES THESE CHANGES.
PL 13689/0022	BICAVERA 2.3% GLUCOSE, 1.25 MMOL/L CALCIUM, SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0022-0006	PL 13689/0022-0006	06/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO EPS IN AN APPROPRIATE MANNER FOLLOWING PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIE. CONSEQUENTLY, IMPACTING THE PIL. THE LEAFLET HAS

										NOT BEEN APPROVED WITH THIS VARIATION AS THE CURRENTLY APPROVED LEAFLET ALREADY INCLUDES THESE CHANGES.
PL 13689/0023	BICAVERA 4.25% GLUCOSE, 1.25 MMOL/L CALCIUM, SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0023-0006	PL 13689/0023-0006	06/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC TO EPS IN AN APPROPRIATE MANNER FOLLOWING PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIE. CONSEQUENTLY, IMPACTING THE PIL. THE LEAFLET HAS NOT BEEN APPROVED WITH THIS VARIATION AS THE CURRENTLY APPROVED LEAFLET ALREADY INCLUDES THESE CHANGES.
PL 00025/0618	ATOZET 10 MG/10 MG, FILM-COATED TABLETS	GRANTED	PL 00025/0618-0023	PL 00025/0618-0023	09/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC TO INCLUDE TEXT REGARDING AN INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMG-COA REDUCTASE INHIBITORS AND DAPTOMYCIN (USED FOR TREATMENT OF COMPLICATED SKIN

										AND SKIN STRUCTURE INFECTIONS AND BACTERAEMIA). IT SHOULD BE CONSIDERED TO SUSPEND THE ADMINISTRATION OF STATIN CONTAINING PRODUCTS, SUCH AS ATOZET (EZETIMIBE & ATORVASTATIN. ADDITIONALLY, SECTIONS 4.6, 4.8, 5.1 AND 5.2 OF THE SMPC HAVE BEEN UPDATED IN LINE WITH THE PRODUCT INFORMATION OF LIPITOR. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00025/0619	ATOZET 10 MG/20 MG, FILM-COATED TABLETS	GRANTED	PL 00025/0619-0023	PL 00025/0619-0023	09/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC TO INCLUDE TEXT REGARDING AN INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMG-COA REDUCTASE INHIBITORS AND DAPTOMYCIN (USED FOR TREATMENT OF

										COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS AND BACTERAEMIA). IT SHOULD BE CONSIDERED TO SUSPEND THE ADMINISTRATION OF STATIN CONTAINING PRODUCTS, SUCH AS ATOZET (EZETIMIBE & ATORVASTATIN. ADDITIONALLY, SECTIONS 4.6, 4.8, 5.1 AND 5.2 OF THE SMPC HAVE BEEN UPDATED IN LINE WITH THE PRODUCT INFORMATION OF LIPITOR. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00025/0620	ATOZET 10 MG/40 MG, FILM-COATED TABLETS	GRANTED	PL 00025/0620-0023	PL 00025/0620-0023	09/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC TO INCLUDE TEXT REGARDING AN INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMG-COA REDUCTASE INHIBITORS AND

										DAPTOMYCIN (USED FOR TREATMENT OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS AND BACTERAEMIA). IT SHOULD BE CONSIDERED TO SUSPEND THE ADMINISTRATION OF STATIN CONTAINING PRODUCTS, SUCH AS ATOZET (EZETIMIBE & ATORVASTATIN. ADDITIONALLY, SECTIONS 4.6, 4.8, 5.1 AND 5.2 OF THE SMPC HAVE BEEN UPDATED IN LINE WITH THE PRODUCT INFORMATION OF LIPITOR. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00025/0621	ATOZET 10 MG/80 MG FILM-COATED TABLETS	GRANTED	PL 00025/0621-0023	PL 00025/0621-0023	09/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC TO INCLUDE TEXT REGARDING AN INCREASED RISK OF MYOPATHY AND/OR RHABDOMYOLYSIS BY CO-ADMINISTRATION OF HMG-COA

										REDUCTASE INHIBITORS AND DAPTOMYCIN (USED FOR TREATMENT OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS AND BACTERAEMIA). IT SHOULD BE CONSIDERED TO SUSPEND THE ADMINISTRATION OF STATIN CONTAINING PRODUCTS, SUCH AS ATOZET (EZETIMIBE & ATORVASTATIN. ADDITIONALLY, SECTIONS 4.6, 4.8, 5.1 AND 5.2 OF THE SMPC HAVE BEEN UPDATED IN LINE WITH THE PRODUCT INFORMATION OF LIPITOR. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 20162/0015	MONOPOST 50 MICROGRAMS/ML EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER	GRANTED	PL 20162/0015-0037	PL 20162/0015-0037	10/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE REFERENCE MEDICINAL PRODUCT XALATAN 0.005%, EYE DROPS, SOLUTION (UK/H/0179/001).

										CONSEQUENTLY, IMPACTING THE PIL. IN ADDITION, UPDATES TO SECTIONS 4.2 AND 4.6 OF THE SPC HAVE BEEN MADE, IN LINE WITH THE LATEST QRD TEMPLATE AND SOME MINOR EDITORIAL CHANGES.
PL 20162/0015	MONOPOST 50 MICROGRAMS/ML EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER	GRANTED	PL 20162/0015-0037	PL 20162/0015-0037	10/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC IN LINE WITH THE REFERENCE MEDICINAL PRODUCT XALATAN 0.005%, EYE DROPS, SOLUTION (UK/H/0179/001). CONSEQUENTLY, IMPACTING THE PIL. IN ADDITION, UPDATES TO SECTIONS 4.2 AND 4.6 OF THE SPC HAVE BEEN MADE, IN LINE WITH THE LATEST QRD TEMPLATE AND SOME MINOR EDITORIAL CHANGES.
PL 00025/0565	NUVARING 0.120 MG/0.015 MG PER 24 HOURS, VAGINAL DELIVERY SYSTEM	GRANTED	PL 00025/0565-0030	PL 00025/0565-0030	11/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.8 AND 6.5 IN LINE WITH THE CCDS. CONSEQUENTIALLY

								WORKSHARING		THE PIL HAS BEEN UPDATED
PL 17901/0132	LOSEC 10 MG HARD GASTRO-RESISTANT CAPSULES	GRANTED	PL 17901/0132-0068	PL 17901/0132-0068	12/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS), 4.5 (INTERACTIONS), 4.8 (UNDESIRABLE EFFECTS) AND 5.1 (PHARMACODYNAMICS) OF THE SPC IN LINE WITH THE LATEST CORE DATA SHEET. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 17901/0133	LOSEC 20 MG HARD GASTRO-RESISTANT CAPSULES	GRANTED	PL 17901/0133-0063	PL 17901/0133-0063	12/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS), 4.5 (INTERACTIONS), 4.8 (UNDESIRABLE EFFECTS) AND 5.1 (PHARMACODYNAMICS) OF THE SPC IN LINE WITH THE LATEST CORE DATA SHEET. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 17901/0134	LOSEC 40 MG HARD GASTRO-RESISTANT CAPSULES	GRANTED	PL 17901/0134-0062	PL 17901/0134-0062	12/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS), 4.5 (INTERACTIONS), 4.8 (UNDESIRABLE EFFECTS) AND 5.1 (PHARMACODYNAMICS) OF THE SPC IN LINE WITH THE LATEST CORE DATA SHEET.

										AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 17901/0137	LOSEC MUPS 10MG GASTRO-RESISTANT TABLETS	GRANTED	PL 17901/0137-0057	PL 17901/0137-0057	12/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS), 4.5 (INTERACTIONS), 4.8 (UNDESIRABLE EFFECTS) AND 5.1 (PHARMACODYNAMICS) OF THE SPC IN LINE WITH THE LATEST CORE DATA SHEET. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 17901/0138	LOSEC MUPS 20MG GASTRO-RESISTANT TABLETS	GRANTED	PL 17901/0138-0055	PL 17901/0138-0055	12/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS), 4.5 (INTERACTIONS), 4.8 (UNDESIRABLE EFFECTS) AND 5.1 (PHARMACODYNAMICS) OF THE SPC IN LINE WITH THE LATEST CORE DATA SHEET. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 17901/0139	LOSEC MUPS 40MG GASTRO-RESISTANT TABLETS	GRANTED	PL 17901/0139-0054	PL 17901/0139-0054	12/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS), 4.5 (INTERACTIONS), 4.8 (UNDESIRABLE EFFECTS) AND 5.1 (PHARMACODYNAMICS) OF THE SPC IN LINE WITH THE LATEST CORE DATA SHEET.

										AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 34111/0001	ALENDRONIC ACID 70 MG ORAL SOLUTION	GRANTED	PL 34111/0001-0037	PL 34111/0001-0037	12/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP FOR ALENDRONIC ACID FROM VERSION 3 TO VERSION 4, IN LINE WITH MODULE V - RISK MANAGEMENT SYSTEMS (REV 2).
PL 14598/0062	SPIRIVA 18 MICROGRAM INHALATION POWDER, HARD CAPSULE	GRANTED	PL 14598/0062-0133	PL 14598/0062-0133	13/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE EU. RISK MANAGEMENT PLAN FROM VERSION 9.0 TO VERSION 10.0 FOR TIOTROPIUM INCLUDING SPIRIVA 18 MICROGRAM, INHALATION POWDER, HARD CAPSULE AND SPIRIVA RESPIMAT ® 2.5 MICROGRAM, INHALATION SOLUTION.
PL 14598/0084	SPIRIVA RESPIMAT 2.5 MICROGRAM, INHALATION SOLUTION	GRANTED	PL 14598/0084-0063	PL 14598/0084-0063	13/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE EU. RISK MANAGEMENT PLAN FROM VERSION 9.0 TO VERSION 10.0 FOR TIOTROPIUM INCLUDING SPIRIVA 18 MICROGRAM, INHALATION POWDER, HARD CAPSULE AND SPIRIVA RESPIMAT ® 2.5 MICROGRAM, INHALATION SOLUTION.
PL 04515/0127	MITOXANTRONE 2 MG/ML CONCENTRATE	GRANTED	PL 04515/0	PL 04515/0	16/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE THE

	FOR SOLUTION FOR INFUSION		127-0060	127-0060				(STANDARD) - CMS		ADDITIONAL ADVERSE DRUG REACTION (ADR) INTERSTITIAL PNEUMONITIS, IN LINE WITH PFIZER¿S COMPANY CORE DATA SHEET. CONSEQUENTLY, THE PRODUCT INFORMATION LEAFLET HAS BEEN UPDATED.
PL 03551/0075	STERILE POTASSIUM CHLORIDE CONCENTRATE (15% W/V) BP	GRANTED	PL 03551/0075-0030	PL 03551/0075-0030	18/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 5.1, 5.2 AND 5.3 OF THE SMPC AND PIL TO BE IN LINE WITH THE CURRENT COMPANY CORE DATA SHEET AND IN LINE WITH THE LATEST QRD TEMPLATE. (A MINOR EDITORIAL UPDATE HAS ALSO BEEN MADE TO SECTION 2 OF THE SPC.). NO CHANGES TO THE LABELLING ARE APPROVED WITH THIS VARIATION.
PL 46302/0033	FAVERIN 100MG FILM-COATED TABLETS	GRANTED	PL 46302/0033-0021	PL 46302/0033-0021	18/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE STEVENS-JOHNSON SYNDROME (SJS) AND TOXIC EPIDERMAL NECROLYSIS (TEN) AS AN ADVERSE REACTION

										FOLLOWING THE REVIEW OF AVAILABLE DATA DESCRIBING SJS AND TEN COINCIDENT WITH FLUVOXAMINE TREATMENT. ADDITIONALLY, INFORMATION ON THE SODIUM CONTENT HAS BEEN ADDED TO SECTION 4.4 OF THE SMPC. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 46302/0034	FAVERIN 50MG FILM-COATED TABLETS	GRANTED	PL 46302/0034-0018	PL 46302/0034-0018	18/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC TO INCLUDE STEVENS-JOHNSON SYNDROME (SJS) AND TOXIC EPIDERMAL NECROLYSIS (TEN) AS AN ADVERSE REACTION FOLLOWING THE REVIEW OF AVAILABLE DATA DESCRIBING SJS AND TEN COINCIDENT WITH FLUVOXAMINE TREATMENT. ADDITIONALLY, INFORMATION ON THE SODIUM CONTENT HAS BEEN ADDED TO SECTION 4.4 OF THE SMPC.

										CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00025/0562	CERAZETTE 75 MICROGRAM FILM-COATED TABLETS	GRANTED	PL 00025/0562-0030	PL 00025/0562-0030	19/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC REGARDING HYPERSENSITIVITY AS AN ADVERSE EVENT IN LINE WITH THE CCDS. THE PACKAGE LEAFLET IS UPDATED ACCORDINGLY.
PL 00057/1280	EFEXOR XL 75MG CAPSULES	GRANTED	PL 00057/1280-0045	PL 00057/1280-0045	19/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC TO ADD THE ADVERSE DRUG REACTION (ADR) ¿TAKOTSUBO CARDIOMYOPATHY¿ IN LINE WITH THE COMPANY CORE DATA SHEET (CDS).
PL 00057/1281	EFEXOR XL 150MG CAPSULES	GRANTED	PL 00057/1281-0043	PL 00057/1281-0043	19/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC TO ADD THE ADVERSE DRUG REACTION (ADR) ¿TAKOTSUBO CARDIOMYOPATHY¿ IN LINE WITH THE COMPANY CORE DATA SHEET (CDS).
PL 00057/1512	EFEXOR XL 225 MG HARD PROLONGED-RELEASE CAPSULES	GRANTED	PL 00057/1512-0016	PL 00057/1512-0016	19/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SPC TO ADD THE ADVERSE DRUG REACTION (ADR) ¿TAKOTSUBO CARDIOMYOPATHY¿ IN LINE WITH THE

										COMPANY CORE DATA SHEET (CDS).
PL 43946/0001	ADRENALINE 1:1000 (1MG/ML) SOLUTION FOR INJECTION	GRANTED	PL 43946/0001-0005	PL 43946/0001-0005	20/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS, 3, 4.2, 4.4, 4.9 , 6.5 AND 7 OF THE SMPC, LABELLING AND PIL TO IMPLEMENT THE COMMENTS RECEIVED BY THE NEW CMSS, ON DAY 30 OF THE REPEAT USE PROCEDURE UK/H/5988/001/E/001. ADDITIONALLY THE INNER AND OUTER LABEL PACKING HAS BEEN AMENDED AS WELL AS TO IMPLEMENT THE STANDARD STATEMENTS ON THE UNIQUE IDENTIFIER AND ITS CARRIER BY COMPLYING WITH THE REVISED QRD TEMPLATE IN ORDER TO PLACE THE SAFETY FEATURES ON THE PACKAGING AND THUS UPDATE THE PRODUCT INFORMATION ACCORDING TO THE NEWEST VERSION 4, 02/2016 QRD TEMPLATE.

PL 19494/0075	DUAC ONCE DAILY 10MG/G + 50MG/G GEL	GRANTED	PL 19494/0075-0073	PL 19494/0075-0073	20/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP FROM VERSION 2.0 TO 2.1, TO MEET THE REQUIREMENTS AND UPDATED DEFINITIONS IN THE REVISIONS TO GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP) MODULE V (EMA/838713/2011; REVISION 2) AND THE ACCOMPANYING RMP TEMPLATE (EMA/PRAC/613102/2015 REV 2).
PL 19494/0251	DUAC ONCE DAILY 10MG/G + 30MG/G GEL	GRANTED	PL 19494/0251-0030	PL 19494/0251-0030	20/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP FROM VERSION 2.0 TO 2.1, TO MEET THE REQUIREMENTS AND UPDATED DEFINITIONS IN THE REVISIONS TO GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP) MODULE V (EMA/838713/2011; REVISION 2) AND THE ACCOMPANYING RMP TEMPLATE (EMA/PRAC/613102/2015 REV 2).
PL 11243/0002	MEDIKINET 5MG TABLETS	GRANTED	PL 11243/0002-0051	PL 11243/0002-0051	27/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION 3.0 TO VERSION 5.6) FOR MEDIKINET 5MG, 10MG, 20MG TABLETS

								CMS WORKSHARING		AND MEDIKINET XL 5 MG, 10 MG, 20 MG, 30 MG, 40 MG, 50 MG & 60 MG MODIFIED-RELEASE CAPSULES, HARD.
PL 11243/0003	MEDIKINET 10MG TABLETS	GRANTED	PL 11243/0003-0050	PL 11243/0003-0050	27/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION 3.0 TO VERSION 5.6) FOR MEDIKINET 5MG, 10MG, 20MG TABLETS AND MEDIKINET XL 5 MG, 10 MG, 20 MG, 30 MG, 40 MG, 50 MG & 60 MG MODIFIED-RELEASE CAPSULES, HARD.
PL 11243/0004	MEDIKINET 20MG TABLETS	GRANTED	PL 11243/0004-0051	PL 11243/0004-0051	27/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION 3.0 TO VERSION 5.6) FOR MEDIKINET 5MG, 10MG, 20MG TABLETS AND MEDIKINET XL 5 MG, 10 MG, 20 MG, 30 MG, 40 MG, 50 MG & 60 MG MODIFIED-RELEASE CAPSULES, HARD.
PL 11243/0005	MEDIKINET XL 10 MG MODIFIED-RELEASE CAPSULES, HARD	GRANTED	PL 11243/0005-0070	PL 11243/0005-0070	27/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION 3.0 TO VERSION 5.6) FOR MEDIKINET 5MG, 10MG, 20MG TABLETS AND MEDIKINET XL 5 MG, 10 MG, 20 MG, 30 MG, 40 MG, 50 MG & 60 MG MODIFIED-RELEASE CAPSULES, HARD.

PL 11243/0006	MEDIKINET XL 20 MG MODIFIED-RELEASE CAPSULES, HARD	GRANTED	PL 11243/0006-0069	PL 11243/0006-0069	27/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION 3.0 TO VERSION 5.6) FOR MEDIKINET 5MG, 10MG, 20MG TABLETS AND MEDIKINET XL 5 MG, 10 MG, 20 MG, 30 MG, 40 MG, 50 MG & 60 MG MODIFIED-RELEASE CAPSULES, HARD.
PL 11243/0007	MEDIKINET XL 30 MG MODIFIED-RELEASE CAPSULES, HARD	GRANTED	PL 11243/0007-0068	PL 11243/0007-0068	27/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION 3.0 TO VERSION 5.6) FOR MEDIKINET 5MG, 10MG, 20MG TABLETS AND MEDIKINET XL 5 MG, 10 MG, 20 MG, 30 MG, 40 MG, 50 MG & 60 MG MODIFIED-RELEASE CAPSULES, HARD.
PL 11243/0008	MEDIKINET XL 40 MG MODIFIED-RELEASE CAPSULES, HARD	GRANTED	PL 11243/0008-0068	PL 11243/0008-0068	27/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION 3.0 TO VERSION 5.6) FOR MEDIKINET 5MG, 10MG, 20MG TABLETS AND MEDIKINET XL 5 MG, 10 MG, 20 MG, 30 MG, 40 MG, 50 MG & 60 MG MODIFIED-RELEASE CAPSULES, HARD.
PL 11243/0010	MEDIKINET XL 5 MG MODIFIED-RELEASE CAPSULES, HARD	GRANTED	PL 11243/0010-0038	PL 11243/0010-0038	27/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION 3.0 TO VERSION 5.6) FOR MEDIKINET 5MG, 10MG, 20MG TABLETS AND MEDIKINET XL 5

								WORKSHARING		MG, 10 MG, 20 MG, 30 MG, 40 MG, 50 MG & 60 MG MODIFIED-RELEASE CAPSULES, HARD.
PL 11243/0011	MEDIKINET XL 50 MG MODIFIED-RELEASE CAPSULE, HARD	GRANTED	PL 11243/0011-0031	PL 11243/0011-0031	27/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION 3.0 TO VERSION 5.6) FOR MEDIKINET 5MG, 10MG, 20MG TABLETS AND MEDIKINET XL 5 MG, 10 MG, 20 MG, 30 MG, 40 MG, 50 MG & 60 MG MODIFIED-RELEASE CAPSULES, HARD.
PL 11243/0012	MEDIKINET XL 60 MG MODIFIED-RELEASE CAPSULE, HARD	GRANTED	PL 11243/0012-0031	PL 11243/0012-0031	27/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP (FROM VERSION 3.0 TO VERSION 5.6) FOR MEDIKINET 5MG, 10MG, 20MG TABLETS AND MEDIKINET XL 5 MG, 10 MG, 20 MG, 30 MG, 40 MG, 50 MG & 60 MG MODIFIED-RELEASE CAPSULES, HARD.
PL 32870/0001	METFORMIN HYDROCHLORIDE 500 MG FILM COATED TABLETS	GRANTED	PL 32870/0001-0043	PL 32870/0001-0043	31/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2,3, 4.2, 4.3, 4.4, 4.5, 4.8, 5.1, 5.2 AND 6.6 AND PIL IN-LINE WITH THE RMP'S TEXT, ADDITIONALLY LABELING TEXTS ARE ALSO UPDATED AS PER THE CURRENT QRD TEMPLATE , FOLLOWING CHANGES ARE MADE AS PER

										APPLICANT'S COMMITMENT DURING RUP.
PL 32870/0002	METFORMIN HYDROCHLORIDE 850 MG FILM COATED TABLETS	GRANTED	PL 32870/0002-0046	PL 32870/0002-0046	31/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2,3, 4.2, 4.3, 4.4, 4.5, 4.8, 5.1, 5.2 AND 6.6 AND PIL IN-LINE WITH THE RMP'S TEXT, ADDITIONALLY LABELING TEXTS ARE ALSO UPDATED AS PER THE CURRENT QRD TEMPLATE , FOLLOWING CHANGES ARE MADE AS PER APPLICANT'S COMMITMENT DURING RUP.
PL 32870/0003	METFORMIN HYDROCHLORIDE 1000 MG FILM COATED TABLETS	GRANTED	PL 32870/0003-0043	PL 32870/0003-0043	31/12/2019	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2,3, 4.2, 4.3, 4.4, 4.5, 4.8, 5.1, 5.2 AND 6.6 AND PIL IN-LINE WITH THE RMP'S TEXT, ADDITIONALLY LABELING TEXTS ARE ALSO UPDATED AS PER THE CURRENT QRD TEMPLATE , FOLLOWING CHANGES ARE MADE AS PER APPLICANT'S COMMITMENT DURING RUP.
PL 20046/0261	PREDNISOLONE 5MG SOLUBLE TABLETS	GRANTED	PL 20046/0261-0018	PL 20046/0261-0018	03/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) ¿	MUTUAL RECOGNITION	TO UPDATE RISK MANAGEMENT PLAN (RMP) FOR THE AFORESAID PRODUCT LICENSES. THE RMP IS

								CMS RMP		BEING UPDATED FROM VERSION 1.0 TO VERSION 2.0 INCLUDING NEW SAFETY CONCERNS IDENTIFIED FOR PREDNISOLONE AS WELL AS ARMM OF STEROID CARD.
PL 00038/0103	AMOXIL CAPSULES 250MG	GRANTED	PL 00038/0103-0094	PL 00038/0103-0094	04/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SPC TO ADD ASEPTIC MENINGITIS TO 'UNDESIRABLE EFFECTS' WITH RELATED CHANGES TO SECTION 4 'POSSIBLE SIDE EFFECTS' OF THE PATIENT LEAFLET.
PL 00057/1270	CELECOXIB 100 MG CAPSULES, HARD	GRANTED	PL 00057/1270-0043	PL 00057/1270-0043	07/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-1, 4-2, 4-3, 4-4, 4-5, 4-8, 5-1, 5-2, 5-3, 6-1, 6-3, 6-4, 9-0 AND PIL WITH NEW TEXT CLARIFYING THAT CO-ADMINISTRATION OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AND ANTIPLATELET DRUGS (AS A CLASS) IS ASSOCIATED WITH AN INCREASED RISK OF GASTROINTESTINAL BLEEDING. EDITORIAL CHANGES ARE ALSO MADE TO THE SMPC AND PIL.

PL 00057/1271	CELECOXIB 200 MG CAPSULES, HARD	GRANTED	PL 00057/1271-0041	PL 00057/1271-0041	07/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-1, 4-2, 4-3, 4-4, 4-5, 4-8, 5-1, 5-2, 5-3, 6-1, 6-3, 6-4, 9-0 AND PIL WITH NEW TEXT CLARIFYING THAT CO-ADMINISTRATION OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AND ANTIPLATELET DRUGS (AS A CLASS) IS ASSOCIATED WITH AN INCREASED RISK OF GASTROINTESTINAL BLEEDING. EDITORIAL CHANGES ARE ALSO MADE TO THE SMPC AND PIL.
PL 00057/1276	CELEBREX 200MG CAPSULES, HARD	GRANTED	PL 00057/1276-0054	PL 00057/1276-0054	07/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-1, 4-2, 4-3, 4-4, 4-5, 4-8, 5-1, 5-2, 5-3, 6-1, 6-3, 6-4, 9-0 AND PIL WITH NEW TEXT CLARIFYING THAT CO-ADMINISTRATION OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AND ANTIPLATELET DRUGS (AS A CLASS) IS ASSOCIATED WITH AN INCREASED RISK OF GASTROINTESTINAL BLEEDING. EDITORIAL CHANGES ARE ALSO MADE TO THE SMPC AND PIL.

PL 15413/0021	IMIPENEM/CILASTATIN 500MG/500MG POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 15413/0021-0042	PL 15413/0021-0042	07/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP IN LINE WITH GVP MODULE V REV 2 AND ALSO LABELLING TEXTS HAVE BEEN UPDATED IN LINE WITH QRD TO MEET REQUIREMENTS OF FMD.
PL 04416/1163	ALENDRONIC ACID AND CALCIUM/CHOLECALCIFEROL 70MG+1000MG/880 IU FILM-COATED TABLETS+ EFFERVESCENT TAB	GRANTED	PL 04416/1163-0044	PL 04416/1163-0044	07/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.5, 4.7 ,4.8, 4.9, 5.2, AND 6.5 OF THE SPC. CONSEQUENTIALLY, THE LABEL AND LEAFLET HAVE BEEN UPDATED.
PL 31750/0049	ESOMEPRAZOLE 40 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 31750/0049-0025	PL 31750/0049-0025	07/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO ADD A RISK MANAGEMENT PLAN TO ESOMEPRAZOLE SUN DOSSIER TO ENSURE COMPLIANCE WITH CURRENT REGULATORY REQUIREMENTS.
PL 00057/1275	CELEBREX 100MG CAPSULES, HARD	GRANTED	PL 00057/1275-0055	PL 00057/1275-0055	07/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-1, 4-2, 4-3, 4-4, 4-5, 4-8, 5-1, 5-2, 5-3, 6-1, 6-3, 6-4, 9-0 AND PIL WITH NEW TEXT CLARIFYING THAT CO-ADMINISTRATION OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AND ANTIPLATELET DRUGS (AS A CLASS) IS ASSOCIATED WITH AN

										INCREASED RISK OF GASTROINTESTINAL BLEEDING. EDITORIAL CHANGES ARE ALSO MADE TO THE SMPC AND PIL.
PL 04854/0157	BENILEXA 20 MICROGRAMS/24 HOURS INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 04854/0157-0027	PL 04854/0157-0027	09/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) AS THE CONSEQUENCE OF PSUFU ASSESSMENT REPORT FOR THE LNG IUS (PROCEDURE NUMBER: DE/H/PSUFU/00001856/201712).
PL 00166/0203	PROGRAF HARD CAPSULES 1MG	GRANTED	PL 00166/0203-0076	PL 00166/0203-0076	15/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.2, 4.4, 4.5, 4.6, 4.8 OF THE SMPC AND PIL IN LINE WITH THE CCDS AND TO IMPLEMENT THE WORDING FROM UPDATED ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON ¿EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE¿ (SANTE-2017-11668). ADDITIONALLY FORMATTING CHANGES HAVE BEEN MADE TO ALIGN WITH

										QRD TEMPLATE AND THE CURRENT APPROVED ARTWORK.
PL 00166/0204	PROGRAF HARD CAPSULES 5MG	GRANTED	PL 00166/0204-0076	PL 00166/0204-0076	15/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.2, 4.4, 4.5, 4.6, 4.8 OF THE SMPC AND PIL IN LINE WITH THE CCDS AND TO IMPLEMENT THE WORDING FROM UPDATED ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON ¿EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE¿ (SANTE-2017-11668). ADDITIONALLY FORMATTING CHANGES HAVE BEEN MADE TO ALIGN WITH QRD TEMPLATE AND THE CURRENT APPROVED ARTWORK.
PL 00166/0205	PROGRAF CONCENTRATE FOR INFUSION 5MG/ML	GRANTED	PL 00166/0205-0069	PL 00166/0205-0069	15/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.2, 4.4, 4.5, 4.6, 4.8 OF THE SMPC AND PIL IN LINE WITH THE CCDS AND TO IMPLEMENT THE WORDING FROM UPDATED ANNEX TO THE EUROPEAN

										COMMISSION GUIDELINE ON ¿EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE¿ (SANTE-2017-11668). ADDITIONALLY FORMATTING CHANGES HAVE BEEN MADE TO ALIGN WITH QRD TEMPLATE AND THE CURRENT APPROVED ARTWORK.
PL 00166/0206	PROGRAF HARD CAPSULES 0.5MG	GRANTED	PL 00166/0206-0075	PL 00166/0206-0075	15/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.2, 4.4, 4.5, 4.6, 4.8 OF THE SMPC AND PIL IN LINE WITH THE CCDS AND TO IMPLEMENT THE WORDING FROM UPDATED ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON ¿EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE¿ (SANTE-2017-11668). ADDITIONALLY FORMATTING CHANGES HAVE BEEN MADE TO ALIGN WITH

										QRD TEMPLATE AND THE CURRENT APPROVED ARTWORK.
PL 12762/0480	PEVANTI 2.5MG TABLETS	GRANTED	PL 12762/0480-0019	PL 12762/0480-0019	16/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN [RMP] FROM VERSION 1.0 TO VERSION 2.0 INCLUDING NEW SAFETY CONCERNS IDENTIFIED FOR PREDNISOLONE AS WELL AS ARMM OF STEROID CARD.
PL 12762/0481	PEVANTI 5MG TABLETS	GRANTED	PL 12762/0481-0017	PL 12762/0481-0017	16/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN [RMP] FROM VERSION 1.0 TO VERSION 2.0 INCLUDING NEW SAFETY CONCERNS IDENTIFIED FOR PREDNISOLONE AS WELL AS ARMM OF STEROID CARD.
PL 12762/0482	PEVANTI 10MG TABLETS	GRANTED	PL 12762/0482-0017	PL 12762/0482-0017	16/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN [RMP] FROM VERSION 1.0 TO VERSION 2.0 INCLUDING NEW SAFETY CONCERNS IDENTIFIED FOR PREDNISOLONE AS WELL AS ARMM OF STEROID CARD.
PL 12762/0483	PEVANTI 20MG TABLETS	GRANTED	PL 12762/0483-0018	PL 12762/0483-0018	16/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN [RMP] FROM VERSION 1.0 TO VERSION 2.0 INCLUDING NEW SAFETY CONCERNS

										IDENTIFIED FOR PREDNISOLONE AS WELL AS ARMM OF STEROID CARD.
PL 12762/0484	PEVANTI 25MG TABLETS	GRANTED	PL 12762/0484-0014	PL 12762/0484-0014	16/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN [RMP] FROM VERSION 1.0 TO VERSION 2.0 INCLUDING NEW SAFETY CONCERNS IDENTIFIED FOR PREDNISOLONE AS WELL AS ARMM OF STEROID CARD.
PL 00057/1293	TAZOCIN 2G/0.25G POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 00057/1293-0055	PL 00057/1293-0055	18/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-2, 4-5, 4-8, 5-1 AND PIL IN LINE WITH THE CCDS, SPECIFICALLY TO ADD DELIRIUM AS AN ADR. EDITORIAL UPDATES HAVE ALSO BEEN MADE, INCLUDING DELETION OF 'ORAL' FROM 'ORAL ANTICOAGULANTS' IN SMPC 4-5. THE LEAFLET WILL BE APPROVED WITH SUBMISSION NUMBER 0059 (IT/H/0675/002/II/040)
PL 00057/1294	TAZOCIN 4G/0.5G POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 00057/1294-0053	PL 00057/1294-0053	18/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-2, 4-5, 4-8, 5-1 AND PIL IN LINE WITH THE CCDS, SPECIFICALLY TO ADD DELIRIUM AS AN ADR. EDITORIAL UPDATES

										HAVE ALSO BEEN MADE, INCLUDING DELETION OF 'ORAL' FROM 'ORAL ANTICOAGULANTS' IN SMPC 4-5. THE LEAFLET WILL BE APPROVED WITH SUBMISSION NUMBER 0059 (IT/H/0675/002/II/040)
PL 14598/0093	STRIVERDI RESPIMAT 2.5 MICROGRAM, INHALATION SOLUTION	GRANTED	PL 14598/0093-0032	PL 14598/0093-0032	20/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE INTERIM REPORT FOR PASS ACCORDING TO OUR POST APPROVAL COMMITMENT. (SECTION M5-3-5-4-OTHER-STUDY-REPORTS)
PL 36390/0211	TENOFOVIR DISOPROXIL 245 MG FILM-COATED TABLETS	GRANTED	PL 36390/0211-0013	PL 36390/0211-0013	20/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP FOR TENOFOVIR DISOPROXIL 245 MG FILM-COATED TABLETS IN LINE WITH GVP MODULE V REV.2 (FROM VERSION 01 TO VERSION 1.1).
PL 04416/1541	ERLOTINIB SANDOZ 25 MG FILM COATED TABLETS	GRANTED	PL 04416/1541-0005	PL 04416/1541-0005	21/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN.
PL 04416/1542	ERLOTINIB SANDOZ 100MG FILM COATED TABLETS	GRANTED	PL 04416/1542-0005	PL 04416/1542-0005	21/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN.

								RD) - CMS		
PL 04416/1543	ERLOTINIB SANDOZ 150 MG FILM COATED TABLETS	GRANTED	PL 04416/1543-0005	PL 04416/1543-0005	21/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN.
PL 04416/1406	RELETRANS 5 MICROGRAM/HOUR TRANSDERMAL PATCH	GRANTED	PL 04416/1406-0017	PL 04416/1406-0017	22/01/2020	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, 4.9, 5.1 AND 5.2 OF THE SMPC AND PIL TO ALIGN WITH THE ORIGINATOR PRODUCT INFORMATION OF REFERENCE PROCEDURE DK/H/0718, NORSPAN, DATED JANUARY 2017.
PL 04416/1407	RELETRANS 10 MICROGRAM/HOUR TRANSDERMAL PATCH	GRANTED	PL 04416/1407-0017	PL 04416/1407-0017	22/01/2020	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, 4.9, 5.1 AND 5.2 OF THE SMPC AND PIL TO ALIGN WITH THE ORIGINATOR PRODUCT INFORMATION OF REFERENCE PROCEDURE DK/H/0718, NORSPAN, DATED JANUARY 2017.
PL 04416/1408	RELETRANS 15 MICROGRAM/HOUR TRANSDERMAL PATCH	GRANTED	PL 04416/1408-0017	PL 04416/1408-0017	22/01/2020	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, 4.9, 5.1 AND 5.2 OF THE SMPC AND PIL TO ALIGN WITH THE ORIGINATOR

										PRODUCT INFORMATION OF REFERENCE PROCEDURE DK/H/0718, NORSPAN, DATED JANUARY 2017.
PL 04416/1409	RELETRANS 20 MICROGRAM/HOUR TRANSDERMAL PATCH	GRANTED	PL 04416/1409-0019	PL 04416/1409-0019	22/01/2020	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, 4.9, 5.1 AND 5.2 OF THE SMPC AND PIL TO ALIGN WITH THE ORIGINATOR PRODUCT INFORMATION OF REFERENCE PROCEDURE DK/H/0718, NORSPAN, DATED JANUARY 2017.
PL 04416/1355	MEMANTINE SANDOZ 10 MG FILM-COATED TABLETS	GRANTED	PL 04416/1355-0019	PL 04416/1355-0019	23/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO ADD A NEW RMP OR MEMANTINE HYDROCHLORIDE 10 MG AND 20 MG, FILM-COATED TABLET WAS CREATED BY THE MARKETING AUTHORIZATION HOLDER UPON THE CLOSURE OF RENEWAL PROCEDURES NL/H/2680-2682+2704/001-002/R/001 WITH THE INTENTION OF REFLECTING THE MOST CURRENT SCIENTIFIC KNOWLEDGE IN THE

										SUMMARY OF SAFETY CONCERNS.
PL 04416/1356	MEMANTINE SANDOZ 20 MG FILM-COATED TABLETS	GRANTED	PL 04416/1356-0022	PL 04416/1356-0022	23/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO ADD A NEW RMP OR MEMANTINE HYDROCHLORIDE 10 MG AND 20 MG, FILM-COATED TABLET WAS CREATED BY THE MARKETING AUTHORIZATION HOLDER UPON THE CLOSURE OF RENEWAL PROCEDURES NL/H/2680-2682+2704/001-002/R/001 WITH THE INTENTION OF REFLECTING THE MOST CURRENT SCIENTIFIC KNOWLEDGE IN THE SUMMARY OF SAFETY CONCERNS.
PL 00057/0551	PRO-EPANUTIN,CONCENTRATE FOR INFUSION|SOLUTION FOR INJECTION	GRANTED	PL 00057/0551-0082	PL 00057/0551-0082	27/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE, OF THE FOSPHENYTOIN SODIUM SUMMARY OF THE SMPC AND SECTION 2 OF THE PIL BY ADDING INFORMATION ON THE EVENT ANGIOEDEMA IN LINE WITH THE LATEST COMPANY

										CORE DATA SHEET (CDS).
PL 00057/0551	PRO-EPANUTIN,CONCENTRATE FOR INFUSION|SOLUTION FOR INJECTION	GRANTED	PL 00057/0551-0083	PL 00057/0551-0083	27/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4.4 AND 4.8 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS), WORDING CONCERNING ACUTE GENERALISED EXANTHEMATOUS PUSTULOSIS (AGEP), AND TO CLARIFY WORDING ON DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS).
PL 04515/0211	GEMCITABINE 200 MG POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 04515/0211-0049	PL 04515/0211-0049	28/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH COMPANY CORE SAFETY INFORMATION WITH CONSEQUENTIAL UPDATE TO SECTION 4 OF THE PATIENT INFORMATION LEAFLET. PRODUCT NOT MARKETED. THE LEAFLET HAS NOT BEEN APPROVED

										WITH THIS SUBMISSION AS THE AGREED TEXT HAS ALREADY BEEN INCLUDED IN THE LATEST APPROVED VERSION OF THE LEAFLET.
PL 04515/0212	GEMCITABINE 1 G POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 04515/0212-0049	PL 04515/0212-0049	28/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH COMPANY CORE SAFETY INFORMATION WITH CONSEQUENTIAL UPDATE TO SECTION 4 OF THE PATIENT INFORMATION LEAFLET. PRODUCT NOT MARKETED. THE LEAFLET HAS NOT BEEN APPROVED WITH THIS SUBMISSION AS THE AGREED TEXT HAS ALREADY BEEN INCLUDED IN THE LATEST APPROVED VERSION OF THE LEAFLET.
PL 04515/0213	GEMCITABINE 2 G POWDER FOR	GRANTED	PL 04515/0	PL 04515/0	28/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC IN LINE WITH COMPANY

	SOLUTION FOR INFUSION		213-0049	213-0049				(STANDARD) - RMS		CORE SAFETY INFORMATION WITH CONSEQUENTIAL UPDATE TO SECTION 4 OF THE PATIENT INFORMATION LEAFLET. PRODUCT NOT MARKETED. THE LEAFLET HAS NOT BEEN APPROVED WITH THIS SUBMISSION AS THE AGREED TEXT HAS ALREADY BEEN INCLUDED IN THE LATEST APPROVED VERSION OF THE LEAFLET.
PL 04569/0658	ONDANSETRON 4MG FILM COATED TABLETS	GRANTED	PL 04569/0658-0042	PL 04569/0658-0042	29/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SUMMARY OF PRODUCT CHARACTERISTICS AND SECTION 4 OF THE PIL IN LINE WITH THE REFERENCE PRODUCT ZOFRAN TABLETS. ADDITIONALLY SOME EDITORIAL CHANGES IN SMPC, LABELLING AND PIL HAS BEEN MADEIN LINE WITH

										THE QRD TEMPLATE, ADAPTATION TO EXCIPIENT GUIDELINES.
PL 04569/0659	ONDANSETRON 8MG FILM COATED TABLETS	GRANTED	PL 04569/0659-0043	PL 04569/0659-0043	29/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SUMMARY OF PRODUCT CHARACTERISTICS AND SECTION 4 OF THE PIL IN LINE WITH THE REFERENCE PRODUCT ZOFRAN TABLETS. ADDITIONALLY SOME EDITORIAL CHANGES IN SMPC, LABELLING AND PIL HAS BEEN MADEIN LINE WITH THE QRD TEMPLATE, ADAPTATION TO EXCIPIENT GUIDELINES.
PL 17907/0305	PARACETAMOL / CAFFEINE 500MG/65MG TABLETS	GRANTED	PL 17907/0305-0017	PL 17907/0305-0017	30/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE RISK MANAGEMENT PLAN FOR - PARACETAMOL / CAFFEINE 500MG/65MG TABLETS
PL 14434/0036	PHENYLEPHRINE 50 MICROGRAMS/ML, SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 14434/0036-0018	PL 14434/0036-0018	30/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP, INSODOING TO MERGE RMP NAP/FR V1.0 APPROVED ON 20-OCT-2014 AND RMP DCP/EU V1.0 APPROVED ON 28-SEP-2015 INTO RMP

										(MERGED) V1.3 DATED 22-OCT-2019.
PL 00156/0322	CLOBAZAM MARTINDALE PHARMA 5MG/5ML ORAL SUSPENSION	GRANTED	PL 00156/0322-0034	PL 00156/0322-0034	31/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE THE RMP TO VERSION 7. IN LINE WITH THE RMP TEMPLATE (REV. 2). [2] TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, FRISIUM TABLETS (PL 04425/0214 - MAH: AVENTIS PHARMA LIMITED). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00156/0322	CLOBAZAM MARTINDALE PHARMA 5MG/5ML ORAL SUSPENSION	GRANTED	PL 00156/0322-0034	PL 00156/0322-0034	31/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE THE RMP TO VERSION 7. IN LINE WITH THE RMP TEMPLATE (REV. 2). [2] TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, FRISIUM TABLETS (PL 04425/0214 - MAH: AVENTIS PHARMA LIMITED). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 00156/0322	TAPCLOB 5MG/5ML ORAL SUSPENSION	GRANTED	PL 00156/0322-0034	PL 00156/0322-0034	31/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE THE RMP TO VERSION 7. IN LINE WITH THE RMP TEMPLATE (REV. 2). [2] TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, FRISIUM TABLETS (PL 04425/0214 - MAH: AVENTIS PHARMA LIMITED). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00156/0322	TAPCLOB 5MG/5ML ORAL SUSPENSION	GRANTED	PL 00156/0322-0034	PL 00156/0322-0034	31/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE THE RMP TO VERSION 7. IN LINE WITH THE RMP TEMPLATE (REV. 2). [2] TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, FRISIUM TABLETS (PL 04425/0214 - MAH: AVENTIS PHARMA LIMITED). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00156/0323	CLOBAZAM MARTINDALE PHARMA	GRANTED	PL 00156/0	PL 00156/0	31/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	[1] TO UPDATE THE RMP TO VERSION 7. IN LINE WITH THE RMP

	10MG/5ML ORAL SUSPENSION		323-0035	323-0035				(STANDARD) - RMS WORKSHARING		TEMPLATE (REV. 2). [2] TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, FRISIUM TABLETS (PL 04425/0214 - MAH: AVENTIS PHARMA LIMITED). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00156/0323	CLOBAZAM MARTINDALE PHARMA 10MG/5ML ORAL SUSPENSION	GRANTED	PL 00156/0323-0035	PL 00156/0323-0035	31/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE THE RMP TO VERSION 7. IN LINE WITH THE RMP TEMPLATE (REV. 2). [2] TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, FRISIUM TABLETS (PL 04425/0214 - MAH: AVENTIS PHARMA LIMITED). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00156/0323	TAPCLOB 10MG/5ML ORAL SUSPENSION	GRANTED	PL 00156/0323-0035	PL 00156/0323-0035	31/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS	MUTUAL RECOGNITION	[1] TO UPDATE THE RMP TO VERSION 7. IN LINE WITH THE RMP TEMPLATE (REV. 2). [2] TO UPDATE

								WORKSHARING		SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, FRISIUM TABLETS (PL 04425/0214 - MAH: AVENTIS PHARMA LIMITED). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00156/0323	TAPCLOB 10MG/5ML ORAL SUSPENSION	GRANTED	PL 00156/0323-0035	PL 00156/0323-0035	31/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE THE RMP TO VERSION 7. IN LINE WITH THE RMP TEMPLATE (REV. 2). [2] TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, FRISIUM TABLETS (PL 04425/0214 - MAH: AVENTIS PHARMA LIMITED). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04569/1341	LESTRAMYL 150 MICROGRAM/20 MICROGRAM TABLETS	GRANTED	PL 04569/1341-0034	PL 04569/1341-0034	31/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE A NEW RISK MANAGEMENT PLAN FOR DESOGESTREL/ETHINYLESTRADIOL TABLETS (NL/H/2102/001-002/DC).

PL 04569/1342	LESTRAMYL 150 MICROGRAM/30 MICROGRAM TABLETS	GRANTED	PL 04569/1342-0035	PL 04569/1342-0035	31/01/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE A NEW RISK MANAGEMENT PLAN FOR DESOGESTREL/ETHINYLESTRADIOL TABLETS (NL/H/2102/001-002/DC).
PL 11648/0257	SAIZEN 5.83MG/ML SOLUTION FOR INJECTION IN CARTRIDGE	GRANTED	PL 11648/0257-0047	PL 11648/0257-0047	01/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 2, 3, 4.6, 5.3 AND 6.5 OF THE SMPC AND PIL FOLLOWING THE SAIZEN SOLUTION FOR INJECTION REPEAT USE PROCEDURE (RUP) IT/H/0025/007-008/E/00 - TO AMEND THE PHARMACEUTICAL FORM FROM ¿SOLUTION FOR INJECTION¿ TO ¿SOLUTION FOR INJECTION IN CARTRIDGE¿.
PL 11648/0258	SAIZEN 8MG/ML SOLUTION FOR INJECTION IN CARTRIDGE	GRANTED	PL 11648/0258-0048	PL 11648/0258-0048	01/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 2, 3, 4.6, 5.3 AND 6.5 OF THE SMPC AND PIL FOLLOWING THE SAIZEN SOLUTION FOR INJECTION REPEAT USE PROCEDURE (RUP) IT/H/0025/007-008/E/00 - TO AMEND THE PHARMACEUTICAL FORM FROM ¿SOLUTION FOR INJECTION¿ TO

										¿SOLUTION FOR INJECTION IN CARTRIDGE¿.
PL 11648/0259	SAIZEN 8 MG CLICK.EASY	GRANTED	PL 11648/0259-0046	PL 11648/0259-0046	01/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 2, 3, 4.6, 5.3 AND 6.5 OF THE SMPC AND PIL FOLLOWING THE SAIZEN SOLUTION FOR INJECTION REPEAT USE PROCEDURE (RUP) IT/H/0025/007-008/E/00 - TO AMEND THE PHARMACEUTICAL FORM FROM ¿SOLUTION FOR INJECTION¿ TO ¿SOLUTION FOR INJECTION IN CARTRIDGE¿.
PL 16853/0147	XONVEA 10MG/10MG GASTRO-RESISTANT TABLETS	GRANTED	PL 16853/0147-0014	PL 16853/0147-0014	05/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5 AND 4.8 OF THE SMPC AS PER REQUEST BY THE REFERENCE MEMBER STATE, HPRA WITH CONSEQUENTIAL UPDATE TO SECTION 4 OF THE PIL
PL 00057/1293	TAZOCIN 2G/0.25G POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 00057/1293-0061	PL 00057/1293-0061	06/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 2-0, 4-4, 4-8 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS), AND WITH EDITORIAL AND EXCIPIENT GUIDELINE UPDATES.

PL 00057/1294	TAZOCIN 4G/0.5G POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 00057/1294-0059	PL 00057/1294-0059	06/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 2-0, 4-4, 4-8 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS), AND WITH EDITORIAL AND EXCIPIENT GUIDELINE UPDATES.
PL 04416/0460	ENALAPRIL MALEATE/HYDROCHLOROTHIAZIDE 20/12.5MG TABLETS	GRANTED	PL 04416/0460-0044	PL 04416/0460-0044	07/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.8, 5.1 AND 5.2 OF THE SMPC AND PIL TO ADOPT TO THE NOT HARMONISED REFERENCE PRODUCT CO-RENITEC, MERCK SHARP & DOHME B.V; NETHERLAND, DATED JANUARY 2019.
PL 00587/0242	SCHOLL ADVANCE ATHLETE'S FOOT CREAM	GRANTED	PL 00587/0242-0058	PL 00587/0242-0058	10/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA. AT THE SAME TIME WE ARE ALSO LOOKING TO INCORPORATE CHANGES FROM THE MOST RECENT RENEWAL IN 2012.
PL 04425/5900R	CLOMID 50MG TABLETS	GRANTED	PL 04425/5900R-0083	PL 04425/5900R-0083	12/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATED 4.4,¿SPECIAL WARNINGS AND PRECAUTIONS FOR USE¿ SECTION 4.8

								WORKSHARING		UNDESIRABLE EFFECTS¿ IN RELATION WITH OVARIAN CANCER AND SECTION 5.3 OF THE SMPC PRECLINICAL SAFETY DATA¿ WITH THE RESULTS OF THE GENOTOXICITY STUDIES WITH CONSEQUENTIAL UPDATED TO PIL TO ACHIEVE A HARMONISED THE OUTCOME OF THE ASSESSMENT AND THE INFORMATION INCLUDED IN THE PRODUCT INFORMATION IN ALL EU CONCERNED MEMBER STATES.
PL 04569/0694	LISINOPRIL AND HYDROCHLOROTHIAZIDE 10MG/12.5MG TABLETS	GRANTED	PL 04569/0694-0055	PL 04569/0694-0055	17/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5, 4-8, 4-9, 5-1, LABEL AND PIL IN LINE WITH THE REFERENCE PRODUCTS ZESTORETIC 10 & 20 MG TABLETS (ASTRAZENECA UK LIMITED), AND WITH NEW CLINICAL DATA: AN INTERNAL SAFETY SIGNAL ON DRUG INTERACTION OF GENERIC ACE INHIBITORS WITH

										NEPRILYS INHIBITORS, WHICH RESULTS IN AN INCREASED RISK OF ANGIOEDEMA.
PL 04569/0694	LISINOPRIL AND HYDROCHLOROTHIAZIDE 10MG/12.5MG TABLETS	GRANTED	PL 04569/0694-0055	PL 04569/0694-0055	17/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5, 4-8, 4-9, 5-1, LABEL AND PIL IN LINE WITH THE REFERENCE PRODUCTS ZESTORETIC 10 & 20 MG TABLETS (ASTRAZENECA UK LIMITED), AND WITH NEW CLINICAL DATA: AN INTERNAL SAFETY SIGNAL ON DRUG INTERACTION OF GENERIC ACE INHIBITORS WITH NEPRILYS INHIBITORS, WHICH RESULTS IN AN INCREASED RISK OF ANGIOEDEMA.
PL 04569/0695	LISINOPRIL AND HYDROCHLOROTHIAZIDE 20 MG/12.5 MG TABLETS	GRANTED	PL 04569/0695-0056	PL 04569/0695-0056	17/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5, 4-8, 4-9, 5-1, LABEL AND PIL IN LINE WITH THE REFERENCE PRODUCTS ZESTORETIC 10 & 20 MG TABLETS (ASTRAZENECA UK LIMITED), AND WITH NEW CLINICAL DATA: AN INTERNAL SAFETY SIGNAL ON DRUG INTERACTION OF GENERIC ACE

										INHIBITORS WITH NEPRILYS INHIBITORS, WHICH RESULTS IN AN INCREASED RISK OF ANGIOEDEMA.
PL 04569/0695	LISINOPRIL AND HYDROCHLOROTHIAZIDE 20 MG/12.5 MG TABLETS	GRANTED	PL 04569/0695-0056	PL 04569/0695-0056	17/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5, 4-8, 4-9, 5-1, LABEL AND PIL IN LINE WITH THE REFERENCE PRODUCTS ZESTORETIC 10 & 20 MG TABLETS (ASTRAZENECA UK LIMITED), AND WITH NEW CLINICAL DATA: AN INTERNAL SAFETY SIGNAL ON DRUG INTERACTION OF GENERIC ACE INHIBITORS WITH NEPRILYS INHIBITORS, WHICH RESULTS IN AN INCREASED RISK OF ANGIOEDEMA.
PL 30883/0007	BETALOC I.V. INJECTION	GRANTED	PL 30883/0007-0006	PL 30883/0007-0006	17/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO HARMONISE THE PRODUCT INFORMATION IN THE UK AND IRELAND AS THERE IS NO SUITABLE ALTERNATIVE OF BETALOC 1MG/ML SOLUTION FOR INJECTION IN THE IRISH MARKET.
PL 11648/0071	CARDICOR 1.25MG FILM-COATED TABLETS	GRANTED	PL 11648/0	PL 11648/0	19/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC TO STRENGTHEN THE

			071-0038	071-0038				(STANDARD) - CMS WORKSHARING		WORDING ON PRINZMETAL'S ANGINA. MINOR CHANGES ARE ALSO MADE TO SECTION 4.8 OF THE SMPC TO ENSURE CONSISTENCY OF MEDDRA PREFERRED TERMS.
PL 11648/0072	CARDICOR 2.5MG FILM-COATED TABLETS	GRANTED	PL 11648/0072-0040	PL 11648/0072-0040	19/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC TO STRENGTHEN THE WORDING ON PRINZMETAL'S ANGINA. MINOR CHANGES ARE ALSO MADE TO SECTION 4.8 OF THE SMPC TO ENSURE CONSISTENCY OF MEDDRA PREFERRED TERMS.
PL 11648/0073	CARDICOR 3.75MG FILM-COATED TABLETS	GRANTED	PL 11648/0073-0039	PL 11648/0073-0039	19/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC TO STRENGTHEN THE WORDING ON PRINZMETAL'S ANGINA. MINOR CHANGES ARE ALSO MADE TO SECTION 4.8 OF THE SMPC TO ENSURE CONSISTENCY OF MEDDRA PREFERRED TERMS.
PL 11648/0074	CARDICOR 5.0MG FILM-COATED TABLETS	GRANTED	PL 11648/0	PL 11648/0	19/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC TO STRENGTHEN THE

			074-0039	074-0039				(STANDARD) - CMS WORKSHARING		WORDING ON PRINZMETAL'S ANGINA. MINOR CHANGES ARE ALSO MADE TO SECTION 4.8 OF THE SMPC TO ENSURE CONSISTENCY OF MEDDRA PREFERRED TERMS.
PL 11648/0075	CARDICOR 7.5MG FILM-COATED TABLETS	GRANTED	PL 11648/0075-0039	PL 11648/0075-0039	19/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC TO STRENGTHEN THE WORDING ON PRINZMETAL'S ANGINA. MINOR CHANGES ARE ALSO MADE TO SECTION 4.8 OF THE SMPC TO ENSURE CONSISTENCY OF MEDDRA PREFERRED TERMS.
PL 11648/0076	CARDICOR 10.0MG FILM-COATED TABLETS	GRANTED	PL 11648/0076-0040	PL 11648/0076-0040	19/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC TO STRENGTHEN THE WORDING ON PRINZMETAL'S ANGINA. MINOR CHANGES ARE ALSO MADE TO SECTION 4.8 OF THE SMPC TO ENSURE CONSISTENCY OF MEDDRA PREFERRED TERMS.
PL 14776/0098	PROVIGIL 100MG TABLETS	GRANTED	PL 14776/0	PL 14776/0	20/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	1.TO UPDATE SECTIONS 4.6 AND 4.8 OF THE SMPC AND

			098-0048	098-0048				(STANDARD) - CMS GROUPING		LABELLING IN LINE WITH THE 'UPDATED SIGNAL ASSESSMENT REPORT ON RISK OF MAJOR CONGENITAL ANOMALY IN WOMEN DURING PREGNANCY WITH MODAFINIL (VIGIL) - EPITT NO: 13937 (EMA/242994/2019)'. 2. TO UPDATE THE RMP TO REFER FURTHER TO THE PREGNANCY REGISTRY FOR NUVIGIL/PROVIGIL AS AN ADDITIONAL PHARMACOVIGILANCE ACTIVITY LINKED TO 'TERATOGENICITY'. 3.TO INCREASE THE FREQUENCY OF PSUR REPORTING TO ONE YEAR AND NOTE THAT THE NEXT PSUR SHOULD COVER THE PERIOD 01/09/2018 TO 31/08/2019.
PL 14776/0098	PROVIGIL 100MG TABLETS	GRANTED	PL 14776/0098-0048	PL 14776/0098-0048	20/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1.TO UPDATE SECTIONS 4.6 AND 4.8 OF THE SMPC AND LABELLING IN LINE WITH THE 'UPDATED SIGNAL ASSESSMENT REPORT ON RISK OF MAJOR CONGENITAL

										ANOMALY IN WOMEN DURING PREGNANCY WITH MODAFINIL (VIGIL) - EPITT NO: 13937 (EMA/242994/2019)'. 2. TO UPDATE THE RMP TO REFER FURTHER TO THE PREGNANCY REGISTRY FOR NUVIGIL/PROVIGIL AS AN ADDITIONAL PHARMACOVIGILANCE ACTIVITY LINKED TO 'TERATOGENICITY'. 3.TO INCREASE THE FREQUENCY OF PSUR REPORTING TO ONE YEAR AND NOTE THAT THE NEXT PSUR SHOULD COVER THE PERIOD 01/09/2018 TO 31/08/2019.
PL 14776/0098	PROVIGIL 100MG TABLETS	GRANTED	PL 14776/0098-0048	PL 14776/0098-0048	20/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1.TO UPDATE SECTIONS 4.6 AND 4.8 OF THE SMPC AND LABELLING IN LINE WITH THE 'UPDATED SIGNAL ASSESSMENT REPORT ON RISK OF MAJOR CONGENITAL ANOMALY IN WOMEN DURING PREGNANCY WITH MODAFINIL (VIGIL) - EPITT NO: 13937

										(EMA/242994/2019)'. 2. TO UPDATE THE RMP TO REFER FURTHER TO THE PREGNANCY REGISTRY FOR NUVIGIL/PROVIGIL AS AN ADDITIONAL PHARMACOVIGILANCE ACTIVITY LINKED TO 'TERATOGENICITY'. 3.TO INCREASE THE FREQUENCY OF PSUR REPORTING TO ONE YEAR AND NOTE THAT THE NEXT PSUR SHOULD COVER THE PERIOD 01/09/2018 TO 31/08/2019.
PL 47513/0008	MELPHALAN 50 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 47513/0008-0002	PL 47513/0008-0002	21/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.3, 4.4 AND 6.5 CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 46302/0055	INFLUVAC SUB-UNIT TETRA, SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 46302/0055-0025	PL 46302/0055-0025	21/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION S4.4, 6.4 AND 6.5 OF THE SMPC, LABELLING AND PIL IN LINE WITH THE COMMENTS OF NEW CMSS DURING THE REPEAT USE PROCEDURE FOR INFLUVAC TETRA WITH PROCEDURE NUMBER NL/H/3844/001/E/001.

										END OF PROCEDURE DATE WAS 18 MARCH 2019. ADDITIONALLY THE PRODUCT INFORMATION HAS BEEN UPDATED IN LINE WITH QRD TEMPLATE.
PL 46302/0056	INFLUENZA VACCINE TETRA MYL, SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 46302/0056-0022	PL 46302/0056-0022	21/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4, 6.4 AND 6.5 OF THE SMPC RESULTING FROM COMMENTS OF NEW CMSS DURING THE REPEAT USE PROCEDURE FOR INFLUVAC TETRA WITH PROCEDURE NUMBER NL/H/3844/001/E/001.
PL 00242/0307	SPORANOX 10 MG/ML ORAL SOLUTION	GRANTED	PL 00242/0307-0107	PL 00242/0307-0107	26/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTION 4.2 OF THE SPC FOR THE REVISION OF THE DOSAGE FOR THE TREATMENT OF ESOPHAGEAL CANDIDOSIS. CONSEQUENTLY, IMPACTING THE PIL. (NOT APPROVED) 2) TO UPDATE SECTION 4.4 OF THE SMPC FOR THE ADDITION OF NEW INFORMATION ON THE TREATMENT OF PATIENTS WITH CYSTIC FIBROSIS.

										CONSEQUENTLY, IMPACTING THE PIL. (APPROVED)
PL 18380/0001	MONOFER 100 MG/ML SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 18380/0001-0049	PL 18380/0001-0049	28/02/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	[1] TO UPDATE SECTIONS 4.4, 4.8 AND 5.1 OF THE SMPC TO INCLUDE NEW CLINICAL DATA AND POST MARKETING SAFETY DATA. [2] TO UPDATE SECTIONS 4.1, 4.2, 4.5, 5.1 AND 6.3 OF THE SMPC TO IMPROVE THE WORDING. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 18727/0012	OXALIPLATIN 5 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 18727/0012-0059	PL 18727/0012-0059	28/02/2020	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, 5.1,5.2 OF THE SMPC AND PIL TO ALIGN WITH ELOXATIN 5 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION- PROCEDURE NUMBER: FR/H/0144/002).
PL 10673/0045	CUTAQUIG, 165 MG/ML, SOLUTION FOR INJECTION	GRANTED	PL 10673/0045-0003	PL 10673/0045-0003	01/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO REVISE SECTION 4.8 OF THE SMPC (AS WELL AS THE CORRESPONDING SECTION IN THE PIL) TO FACILITATE A COMPARISON OF THE SAFETY DATA OF THE

										DIFFERENT SCIG PRODUCTS AVAILABLE ON THE MARKET AND TO PROVIDE HEALTHCARE PROFESSIONALS AS WELL AS PATIENTS SELF-INFUSING CUTAQUIG AT HOME WITH A REAL-LIFE SAFETY PROFILE. CONSEQUENTLY, SMPC SECTION 4.8 AND THE PIL HAVE BEEN UPDATED.
PL 02855/0263	NICABATE EXTRA FRESH MINT 2 MG MEDICATED CHEWING GUM	GRANTED	PL 02855/0263-0024	PL 02855/0263-0024	03/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4.3, 4.4, 4.8, LABEL AND PIL IN LINE WITH NEW PHARMACOVIGILANCE DATA, PLUS QRD, EXCIPIENT GUIDELINE AND EDITORIAL CHANGES.
PL 02855/0264	NICABATE EXTRA FRESH MINT 4 MG MEDICATED CHEWING GUM	GRANTED	PL 02855/0264-0023	PL 02855/0264-0023	03/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4.3, 4.4, 4.8, LABEL AND PIL IN LINE WITH NEW PHARMACOVIGILANCE DATA, PLUS QRD, EXCIPIENT GUIDELINE AND EDITORIAL CHANGES.
PL 02855/0261	NICABATE TROPICAL FLAVOUR 4 MG MEDICATED CHEWING GUM	GRANTED	PL 02855/0261-0029	PL 02855/0261-0029	04/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.3 AND 4.8 OF THE SMPC FOLLOWING NEW PHARMACOVIGILANCE DATA.

								GROUPING		ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 02855/0262	NICABATE TROPICAL FLAVOUR 2 MG MEDICATED CHEWING GUM	GRANTED	PL 02855/0262-0030	PL 02855/0262-0030	04/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	TO UPDATE SECTIONS 4.3 AND 4.8 OF THE SMPC FOLLOWING NEW PHARMACOVIGILANCE DATA. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04425/0214	FRISIUM TABLETS 10MG	GRANTED	PL 04425/0214-0075	PL 04425/0214-0075	04/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.6 OF THE SPC AND PIL TO ACHIEVE A HARMONISED UPDATE OF THE ¿PREGNANCY - RELATED¿ SECTIONS IN THE PRODUCT INFORMATION.

PL 04425/0199	DEPAKOTE 250MG TABLETS	GRANTED	PL 04425/0199-0088	PL 04425/0199-0088	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0200	DEPAKOTE 500MG TABLETS	GRANTED	PL 04425/0200-0093	PL 04425/0200-0093	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO

										MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0300	EPILIM LIQUID 200MG/5ML	GRANTED	PL 04425/0300-0069	PL 04425/0300-0069	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0301	EPILIM SYRUP 200MG/5ML	GRANTED	PL 04425/0301-0077	PL 04425/0301-0077	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31

										JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0302	EPILIM 200 GASTRO-RESISTANT TABLETS	GRANTED	PL 04425/0302-0086	PL 04425/0302-0086	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.

PL 04425/0303	EPILIM 500 GASTRO-RESISTANT TABLETS	GRANTED	PL 04425/0303-0083	PL 04425/0303-0083	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0307	EPILIM CHRONO 200MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0307-0089	PL 04425/0307-0089	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO

										MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0308	EPILIM CHRONO 300MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0308-0096	PL 04425/0308-0096	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0309	EPILIM CHRONO 500MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0309-0088	PL 04425/0309-0088	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31

										JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0310	EPILIM CHRONOSPHERE MR 50 MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0310-0091	PL 04425/0310-0091	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.

PL 04425/0312	EPILIM CHRONOSPHERE MR 100MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0312-0094	PL 04425/0312-0094	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0313	EPILIM CHRONOSPHERE MR 250MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0313-0092	PL 04425/0313-0092	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO

										MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0314	EPILIM CHRONOSPHERE MR 500MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0314-0094	PL 04425/0314-0094	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0315	EPILIM CHRONOSPHERE MR 750MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0315-0093	PL 04425/0315-0093	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31

										JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 04425/0316	EPILIM CHRONOSPHERE MR 1000MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0316-0091	PL 04425/0316-0091	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.

PL 04425/0317	EPILIM 100MG CRUSHABLE TABLETS	GRANTED	PL 04425/0317-0075	PL 04425/0317-0075	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 14040/0024	EPISENTA 150 MG PROLONGED-RELEASE CAPSULE	GRANTED	PL 14040/0024-0048	PL 14040/0024-0048	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO

										MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 14040/0025	EPISENTA 300 MG PROLONGED-RELEASE CAPSULE	GRANTED	PL 14040/0025-0047	PL 14040/0025-0047	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 14040/0026	EPISENTA 500 MG PROLONGED-RELEASE GRANULES	GRANTED	PL 14040/0026-0048	PL 14040/0026-0048	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31

										JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 14040/0027	EPISENTA 1000 MG PROLONGED-RELEASE GRANULES	GRANTED	PL 14040/0027-0047	PL 14040/0027-0047	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.

PL 21597/0002	CONVULEX CAPSULES 300MG	GRANTED	PL 21597/0002-0033	PL 21597/0002-0033	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 21597/0003	CONVULEX CAPSULES 500MG	GRANTED	PL 21597/0003-0032	PL 21597/0003-0032	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO

										MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 21597/0004	CONVULEX CAPSULES 150MG	GRANTED	PL 21597/0004-0034	PL 21597/0004-0034	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 21597/0005	EPIVAL CR 300MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21597/0005-0036	PL 21597/0005-0036	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31

										JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 21597/0006	EPIVAL CR 500MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21597/0006-0035	PL 21597/0006-0035	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.

PL 29831/0188	ORLEPT (SF) LIQUID	GRANTED	PL 29831/0188-0053	PL 29831/0188-0053	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 29831/0188	SODIUM VALPROATE WOCKHARDT 40MG/ML ORAL SOLUTION (SUGAR FREE)	GRANTED	PL 29831/0188-0053	PL 29831/0188-0053	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO

										MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 29831/0189	ORLEPT 200MG GASTRO-RESISTANT TABLETS	GRANTED	PL 29831/0189-0053	PL 29831/0189-0053	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 29831/0189	SODIUM VALPROATE WOCKHARDT 200MG GASTRO-RESISTANT TABLETS	GRANTED	PL 29831/0189-0053	PL 29831/0189-0053	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31

										JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 29831/0190	ORLEPT 500MG GASTRO-RESISTANT TABLETS	GRANTED	PL 29831/0190-0053	PL 29831/0190-0053	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.

PL 29831/0190	SODIUM VALPROATE WOCKHARDT 500MG GASTRO-RESISTANT TABLETS	GRANTED	PL 29831/0190-0053	PL 29831/0190-0053	09/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING - TO ADDRESS THE CMDH REQUEST DATED 31 JANUARY 2O18 ASKING FOR PROVISION OF ADDITIONAL ANALYSIS AND LITERATURE REVIEW (IN RELATION TO A CONDITION TO MARKETING AUTHORIZATION FOLLOWING ARTICLE 37 REFERRAL EMEA/H/A-31/1454 FOR VALPROATE AND RELATED SUBSTANCE.
PL 11648/0054	GETEMIN SR 500MG PROLONGED RELEASE TABLETS	GRANTED	PL 11648/0054-0072	PL 11648/0054-0072	10/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR METFORMIN (MONO-PRODUCT) ACROSS THE EU FOR ALL PRODUCTS AFFECTED: - GLUCOPHAGE® 500/850/1000 MG FILM-COATED TABLETS (METFORMIN HYDROCHLORIDE) - GLUCOPHAGE® XR

										500/750/1000 MG PROLONGED-RELEASE TABLETS (METFORMIN HYDROCHLORIDE) - STAGID® 700 MG TABLETS (METFORMIN EMBONATE)
PL 11648/0054	GLUCOPHAGE SR 500MG PROLONGED RELEASE TABLETS	GRANTED	PL 11648/0054-0072	PL 11648/0054-0072	10/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR METFORMIN (MONO-PRODUCT) ACROSS THE EU FOR ALL PRODUCTS AFFECTED: - GLUCOPHAGE® 500/850/1000 MG FILM-COATED TABLETS (METFORMIN HYDROCHLORIDE) - GLUCOPHAGE® XR 500/750/1000 MG PROLONGED-RELEASE TABLETS (METFORMIN HYDROCHLORIDE) - STAGID® 700 MG TABLETS (METFORMIN EMBONATE)
PL 11648/0066	GLUCOPHAGE SR 750 MG PROLONGED RELEASE TABLETS	GRANTED	PL 11648/0066-0052	PL 11648/0066-0052	10/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR METFORMIN (MONO-PRODUCT) ACROSS

								CMS WORKSHARING		THE EU FOR ALL PRODUCTS AFFECTED: - GLUCOPHAGE® 500/850/1000 MG FILM-COATED TABLETS (METFORMIN HYDROCHLORIDE) - GLUCOPHAGE® XR 500/750/1000 MG PROLONGED-RELEASE TABLETS (METFORMIN HYDROCHLORIDE) - STAGID® 700 MG TABLETS (METFORMIN EMBONATE)
PL 11648/0067	GLUCOPHAGE SR 1000 MG PROLONGED RELEASE TABLETS	GRANTED	PL 11648/0067-0050	PL 11648/0067-0050	10/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR METFORMIN (MONO-PRODUCT) ACROSS THE EU FOR ALL PRODUCTS AFFECTED: - GLUCOPHAGE® 500/850/1000 MG FILM-COATED TABLETS (METFORMIN HYDROCHLORIDE) - GLUCOPHAGE® XR 500/750/1000 MG PROLONGED-RELEASE TABLETS

										(METFORMIN HYDROCHLORIDE) - STAGID® 700 MG TABLETS (METFORMIN EMBONATE)
PL 11648/0085	GLUCOPHAGE 500MG TABLETS	GRANTED	PL 11648/0085-0043	PL 11648/0085-0043	10/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR METFORMIN (MONO-PRODUCT) ACROSS THE EU FOR ALL PRODUCTS AFFECTED: - GLUCOPHAGE® 500/850/1000 MG FILM-COATED TABLETS (METFORMIN HYDROCHLORIDE) - GLUCOPHAGE® XR 500/750/1000 MG PROLONGED-RELEASE TABLETS (METFORMIN HYDROCHLORIDE) - STAGID® 700 MG TABLETS (METFORMIN EMBONATE)
PL 11648/0086	GLUCOPHAGE 850MG TABLETS	GRANTED	PL 11648/0086-0045	PL 11648/0086-0045	10/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FOR METFORMIN (MONO-PRODUCT) ACROSS THE EU FOR ALL PRODUCTS AFFECTED:

										- GLUCOPHAGE® 500/850/1000 MG FILM-COATED TABLETS (METFORMIN HYDROCHLORIDE) - GLUCOPHAGE® XR 500/750/1000 MG PROLONGED-RELEASE TABLETS (METFORMIN HYDROCHLORIDE) - STAGID® 700 MG TABLETS (METFORMIN EMBONATE)
PL 21039/0026	LUBION 25 MG SOLUTION FOR INJECTION	GRANTED	PL 21039/0026-0030	PL 21039/0026-0030	11/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO SUBMIT UPDATED RMP WITH A VIEW OF A FUTURE REPEAT USE PROCEDURE TO INCLUDE NEW CMS
PL 04509/0031	POVIDONE-IODINE 7.5% W/W SURGICAL SCRUB	GRANTED	PL 04509/0031-0029	PL 04509/0031-0029	13/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK ASSESSMENT FOLLOWING THE NEW CMDH CLASSIFICATION OF DIETHANOLAMINE AND COCONUT OIL DIETHANOLAMINE CONDENSATE IN THE MEDICINAL PRODUCT.
PL 18727/0013	BICALUTAMIDE 50 MG FILM-COATED TABLETS	GRANTED	PL 18727/0013-0054	PL 18727/0013-0054	18/03/2020	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, LABELLING AND PIL TO ALIGN WITH THE

										REFERENCE PRODUCT (CASODEX 50 MG FILM-COATED TABLETS).
PL 04425/0627	ORUVAIL 2.5% GEL	GRANTED	PL 04425/0627-0035	PL 04425/0627-0035	18/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE CCDS V5.
PL 08081/0050	ELVANSE 30MG CAPSULES, HARD	GRANTED	PL 08081/0050-0040	PL 08081/0050-0040	20/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) ACCORDING TO THE NEW EU TEMPLATE AND REFLECTING THE CHANGES REQUESTED DURING THE ELVANSE PAEDIATRIC RUP FOR NL, BE, LUX (SE/H/1839/01-06/E/02).
PL 08081/0051	ELVANSE 50 MG CAPSULES, HARD	GRANTED	PL 08081/0051-0041	PL 08081/0051-0041	20/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) ACCORDING TO THE NEW EU TEMPLATE AND REFLECTING THE CHANGES REQUESTED DURING THE ELVANSE PAEDIATRIC RUP FOR NL, BE, LUX (SE/H/1839/01-06/E/02).
PL 08081/0052	ELVANSE 70 MG CAPSULES, HARD	GRANTED	PL 08081/0	PL 08081/0	20/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) ACCORDING TO

			052-0041	052-0041				(STANDARD) - CMS		THE NEW EU TEMPLATE AND REFLECTING THE CHANGES REQUESTED DURING THE ELVANSE PAEDIATRIC RUP FOR NL, BE, LUX (SE/H/1839/01-06/E/02).
PL 08081/0062	ELVANSE 20 MG CAPSULES, HARD	GRANTED	PL 08081/0062-0019	PL 08081/0062-0019	20/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) ACCORDING TO THE NEW EU TEMPLATE AND REFLECTING THE CHANGES REQUESTED DURING THE ELVANSE PAEDIATRIC RUP FOR NL, BE, LUX (SE/H/1839/01-06/E/02).
PL 08081/0063	ELVANSE 40 MG CAPSULES, HARD	GRANTED	PL 08081/0063-0019	PL 08081/0063-0019	20/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) ACCORDING TO THE NEW EU TEMPLATE AND REFLECTING THE CHANGES REQUESTED DURING THE ELVANSE PAEDIATRIC RUP FOR NL, BE, LUX (SE/H/1839/01-06/E/02).
PL 08081/0064	ELVANSE 60 MG CAPSULES, HARD	GRANTED	PL 08081/0064-0019	PL 08081/0064-0019	20/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) ACCORDING TO THE NEW EU TEMPLATE AND REFLECTING THE

										CHANGES REQUESTED DURING THE ELVANSE PAEDIATRIC RUP FOR NL, BE, LUX (SE/H/1839/01-06/E/02).
PL 04425/0199	DEPAKOTE 250MG TABLETS	GRANTED	PL 04425/0199-0090	PL 04425/0199-0090	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0200	DEPAKOTE 500MG TABLETS	GRANTED	PL 04425/0200-0095	PL 04425/0200-0095	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0300	EPILIM LIQUID 200MG/5ML	GRANTED	PL 04425/0300-0071	PL 04425/0300-0071	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO

								WORKSHARING		A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0301	EPILIM SYRUP 200MG/5ML	GRANTED	PL 04425/0301-0079	PL 04425/0301-0079	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0302	EPILIM 200 GASTRO-RESISTANT TABLETS	GRANTED	PL 04425/0302-0088	PL 04425/0302-0088	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.

PL 04425/0303	EPILIM 500 GASTRO-RESISTANT TABLETS	GRANTED	PL 04425/0303-0085	PL 04425/0303-0085	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0307	EPILIM CHRONO 200MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0307-0091	PL 04425/0307-0091	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0308	EPILIM CHRONO 300MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0308-0098	PL 04425/0308-0098	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO

										ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0309	EPILIM CHRONO 500MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0309-0090	PL 04425/0309-0090	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0310	EPILIM CHRONOSPHERE MR 50 MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0310-0093	PL 04425/0310-0093	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0312	EPILIM CHRONOSPHERE MR 100MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0312-0096	PL 04425/0312-0096	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE

										RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0313	EPILIM CHRONOSPHERE MR 250MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0313-0094	PL 04425/0313-0094	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0314	EPILIM CHRONOSPHERE MR 500MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0314-0096	PL 04425/0314-0096	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0315	EPILIM CHRONOSPHERE MR 750MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0315-0095	PL 04425/0315-0095	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO

								WORKSHARING		A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0316	EPILIM CHRONOSPHERE MR 1000MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0316-0093	PL 04425/0316-0093	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0317	EPILIM 100MG CRUSHABLE TABLETS	GRANTED	PL 04425/0317-0077	PL 04425/0317-0077	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.

PL 04425/0685	EPILIM 400MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 04425/0685-0058	PL 04425/0685-0058	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-6 AND PIL IN LINE WITH DATA RECENTLY MADE AVAILABLE, CORRESPONDING TO A PUBLICATION FROM J. CHRISTENSEN ET AL. (2019) ON THE RISK OF ADHD IN CHILDREN EXPOSED IN UTERO TO ANTIEPILEPTIC DRUGS, INCLUDING VALPROATE.
PL 04425/0199	DEPAKOTE 250MG TABLETS	GRANTED	PL 04425/0199-0089	PL 04425/0199-0089	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.

PL 04425/0200	DEPAKOTE 500MG TABLETS	GRANTED	PL 04425/0200-0094	PL 04425/0200-0094	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0300	EPILIM LIQUID 200MG/5ML	GRANTED	PL 04425/0300-0070	PL 04425/0300-0070	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA,

										CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0301	EPILIM SYRUP 200MG/5ML	GRANTED	PL 04425/0301-0078	PL 04425/0301-0078	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0302	EPILIM 200 GASTRO-RESISTANT TABLETS	GRANTED	PL 04425/0302-0087	PL 04425/0302-0087	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF

										BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0303	EPILIM 500 GASTRO-RESISTANT TABLETS	GRANTED	PL 04425/0303-0084	PL 04425/0303-0084	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.

PL 04425/0307	EPILIM CHRONO 200MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0307-0090	PL 04425/0307-0090	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0308	EPILIM CHRONO 300MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0308-0097	PL 04425/0308-0097	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA,

										CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0309	EPILIM CHRONO 500MG CONTROLLED RELEASE TABLETS	GRANTED	PL 04425/0309-0089	PL 04425/0309-0089	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0310	EPILIM CHRONOSPHERE MR 50 MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0310-0092	PL 04425/0310-0092	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF

										BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0312	EPILIM CHRONOSPHERE MR 100MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0312-0095	PL 04425/0312-0095	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.

PL 04425/0313	EPILIM CHRONOSPHERE MR 250MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0313-0093	PL 04425/0313-0093	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0314	EPILIM CHRONOSPHERE MR 500MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0314-0095	PL 04425/0314-0095	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA,

										CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0315	EPILIM CHRONOSPHERE MR 750MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0315-0094	PL 04425/0315-0094	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0316	EPILIM CHRONOSPHERE MR 1000MG MODIFIED RELEASE GRANULES	GRANTED	PL 04425/0316-0092	PL 04425/0316-0092	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF

										BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04425/0317	EPILIM 100MG CRUSHABLE TABLETS	GRANTED	PL 04425/0317-0076	PL 04425/0317-0076	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.

PL 04425/0685	EPILIM 400MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 04425/0685-0057	PL 04425/0685-0057	23/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-6 AND 5-3 IN LINE WITH REPORTS OF AN AMES TEST AND IN VITRO MOUSE LYMPHOMA ASSAY TO INDICATE FOR THE OCCURRENCE OF BOTH GENE MUTATIONS AND CLASTOGENICITY, EXISTING DATA ON CARCINOGENICITY, AND RECENTLY AVAILABLE DATA, CORRESPONDING TO 2 PUBLICATIONS (CHOI ET AL, 2016 AND TARTAGLIONE ET AL, 2018) CONCERNING REPRODUCTIVE TOXICITY.
PL 04416/1600	EBETREX 10MG/ML SOLUTION FOR INJECTION, PRE-FILLED SYRINGE	GRANTED	PL 04416/1600-0004	PL 04416/1600-0004	25/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FOR METHOTREXATE 10 MG/ML SOLUTION FOR INJECTION, PRE-FILLED SYRINGE - FOLLOWING THE OUTCOME OF RECOMMENDATION BY PRAC UNDER ARTICLE 31 REFERRAL (EMA/521627/2019)
PL 00010/0547	MIRENA 20 MICROGRAMS / 24 HOURS INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 00010/0547-0082	PL 00010/0547-0082	25/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO INTRODUCE A NEW RMP (VERSION 1.1) FOR MIRENA 20 MICROGRAMS / 24

								RD) - CMS WORKSHARING		HOURS INTRAUTERINE DELIVERY SYSTEM, AS REQUESTED BY THE PSUSA FOLLOW-UP OUTCOME (DE/H/PSUFU/00001856/201712-PART I, FINALISED AFTER CMDH DISCUSSION ON 28 MARCH 2019).
PL 04416/1162	ALENDRONIC ACID AND CALCIUM/CHOLECALCIFEROL 70MG+1000MG/880 IU FILM-COATED TABLETS+ EFFERVESCENT TAB	GRANTED	PL 04416/1162-0045	PL 04416/1162-0045	25/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.1, 6.5 OF THE SMPC AND PIL
PL 14894/0565	MONTELUKAST RANBAXY 4 MG CHEWABLE TABLETS	GRANTED	PL 14894/0565-0025	PL 14894/0565-0025	25/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2 AND 6.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT SINGULAIR 4, SINGULAIR 5, TABLETKI DO ROZGRYZANIA I żUCIA, MAH: MSD POLSKA SP. Z O.O., MARKETING AUTHORIZATIONS, NOS.: 08780, 07956.
PL 14894/0566	MONTELUKAST RANBAXY 5 MG CHEWABLE TABLETS	GRANTED	PL 14894/0566-0030	PL 14894/0566-0030	25/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2 AND 6.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE

										PRODUCT SINGULAIR 4, SINGULAIR 5, TABLETKI DO ROZGRYZANIA I żUCIA, MAH: MSD POLSKA SP. Z O.O., MARKETING AUTHORIZATIONS, NOS.: 08780, 07956.
PL 46602/0017	QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	GRANTED	PL 46602/0017-0036	PL 46602/0017-0036	26/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND RISK MANAGEMENT PLAN FOLLOWING THE COMPLETION OF GQM14 STUDY. 2) TO PRODUCT INFORMATION AND RISK MANAGEMENT PLAN TO APPROPRIATELY REFLECT ACCUMULATING POST-MARKETING SAFETY DATA REPORTED FOLLOWING THE USE OF QUADRIVALENT INFLUENZA VACCINE (VAXIGRIP TETRA) SINCE THE FIRST LAUNCH OF THE VACCINE IN JULY 2017 AND UP TO 15 MARCH 2019.

										3) TO UPDATE RISK MANAGEMENT PLAN: RECLASSIFICATION OF SAFETY CONCERNS AS PER GVP MODULE V REVISION . THIS WAS ALSO STATED IN THE PBRER WITH A DLP AS OF 15 MARCH 2019.
PL 46602/0017	QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	GRANTED	PL 46602/0017-0036	PL 46602/0017-0036	26/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND RISK MANAGEMENT PLAN FOLLOWING THE COMPLETION OF GQM14 STUDY. 2) TO PRODUCT INFORMATION AND RISK MANAGEMENT PLAN TO APPROPRIATELY REFLECT ACCUMULATING POST-MARKETING SAFETY DATA REPORTED FOLLOWING THE USE OF QUADRIVALENT INFLUENZA VACCINE (VAXIGRIP TETRA) SINCE THE FIRST

										LAUNCH OF THE VACCINE IN JULY 2017 AND UP TO 15 MARCH 2019. 3) TO UPDATE RISK MANAGEMENT PLAN: RECLASSIFICATION OF SAFETY CONCERNS AS PER GVP MODULE V REVISION . THIS WAS ALSO STATED IN THE PBRER WITH A DLP AS OF 15 MARCH 2019.
PL 46602/0017	QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED) SUSPENSION FOR INJ. IN PRE-FILLED SYRINGE	GRANTED	PL 46602/0017-0036	PL 46602/0017-0036	26/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND RISK MANAGEMENT PLAN FOLLOWING THE COMPLETION OF GQM14 STUDY. 2) TO PRODUCT INFORMATION AND RISK MANAGEMENT PLAN TO APPROPRIATELY REFLECT ACCUMULATING POST-MARKETING SAFETY DATA REPORTED

										FOLLOWING THE USE OF QUADRIVALENT INFLUENZA VACCINE (VAXIGRIP TETRA) SINCE THE FIRST LAUNCH OF THE VACCINE IN JULY 2017 AND UP TO 15 MARCH 2019. 3) TO UPDATE RISK MANAGEMENT PLAN: RECLASSIFICATION OF SAFETY CONCERNS AS PER GVP MODULE V REVISION . THIS WAS ALSO STATED IN THE PBRER WITH A DLP AS OF 15 MARCH 2019.
PL 46602/0017	QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED) SUSPENSION FOR INJ. IN PRE-FILLED SYRINGE	GRANTED	PL 46602/0017-0036	PL 46602/0017-0036	26/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND RISK MANAGEMENT PLAN FOLLOWING THE COMPLETION OF GQM14 STUDY. 2) TO PRODUCT INFORMATION AND RISK MANAGEMENT PLAN TO APPROPRIATELY

										REFLECT ACCUMULATING POST-MARKETING SAFETY DATA REPORTED FOLLOWING THE USE OF QUADRIVALENT INFLUENZA VACCINE (VAXIGRIP TETRA) SINCE THE FIRST LAUNCH OF THE VACCINE IN JULY 2017 AND UP TO 15 MARCH 2019. 3) TO UPDATE RISK MANAGEMENT PLAN: RECLASSIFICATION OF SAFETY CONCERNS AS PER GVP MODULE V REVISION . THIS WAS ALSO STATED IN THE PBRER WITH A DLP AS OF 15 MARCH 2019.
PL 00057/0589	SAYANA 104 MG/0.65 ML SUSPENSION FOR INJECTION	GRANTED	PL 00057/0589-0078	PL 00057/0589-0078	26/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	CORRECTIONS OF SMPC AND PL, INCLUSION OF NUMERICAL INFORMATION IN TABLES SECTION 5.1.

PL 00057/0965	DEPO-PROVERA INJECTION 150MG/ML	GRANTED	PL 00057/0965-0028	PL 00057/0965-0028	26/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	CORRECTIONS OF SMPC AND PL, INCLUSION OF NUMERICAL INFORMATION IN TABLES SECTION 5.1.
PL 00057/1093	SAYANA PRESS 104 MG/0.65 ML SUSPENSION FOR INJECTION	GRANTED	PL 00057/1093-0054	PL 00057/1093-0054	26/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	CORRECTIONS OF SMPC AND PL, INCLUSION OF NUMERICAL INFORMATION IN TABLES SECTION 5.1.
PL 00057/1498	SAYANAJECT 104 MG SUSPENSION FOR INJECTION	GRANTED	PL 00057/1498-0028	PL 00057/1498-0028	26/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	CORRECTIONS OF SMPC AND PL, INCLUSION OF NUMERICAL INFORMATION IN TABLES SECTION 5.1.
PL 00057/1500	ELASHINE 104 MG SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 00057/1500-0031	PL 00057/1500-0031	26/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	CORRECTIONS OF SMPC AND PL, INCLUSION OF NUMERICAL INFORMATION IN TABLES SECTION 5.1.
PL 04416/1235	AZITHROMYCIN 250MG TABLETS	GRANTED	PL 04416/1235-0028	PL 04416/1235-0028	26/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.3, 4.4, 4.5, 4.7, 4.8 AND 4.9 OF THE SMPC IN LINE WITH THE NOT HARMONISED REFERENCE PRODUCT,

										ZITHROMAX® 500 MG - FILMTABLETTEN (MAH: PFIZER CORPORATION AUSTRIA GMBH). ADDITIONAL MINOR EDITORIAL CHANGES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 08081/0040	MEZAVANT XL 1200MG, GASTRO-RESISTANT, PROLONGED RELEASE TABLETS	GRANTED	PL 08081/0040-0037	PL 08081/0040-0037	27/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.5 AND 4.6 OF THE SMPC IN LINE WITH THE CCDS VERSION 20. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00240/0381	CARE ANTIFUNGAL 5% W/V MEDICATED NAIL LACQUER	GRANTED	PL 00240/0381-0012	PL 00240/0381-0012	27/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC 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 AND PIL IN LINE WITH THE REFERENCE PRODUCT CURANAIL 5% W/V MEDICATED NAIL LACQUER.

PL 00057/0289	DIFLUCAN 50MG HARD CAPSULES	GRANTED	PL 00057/0289-0137	PL 00057/0289-0137	27/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 AND 4.8 OF THE SMPC AND SECTION 2 OF THE PIL WITH INFORMATION REGARDING DRUG-DRUG INTERACTION BETWEEN FLUCONAZOLE AND IBRUTINIB IN LINE WITH THE FRENCH MEDICAL INTERACTION THESAURUS (PUBLISHED IN MAY 2018).
PL 00057/0290	DIFLUCAN 150MG HARD CAPSULES	GRANTED	PL 00057/0290-0114	PL 00057/0290-0114	27/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 AND 4.8 OF THE SMPC AND SECTION 2 OF THE PIL WITH INFORMATION REGARDING DRUG-DRUG INTERACTION BETWEEN FLUCONAZOLE AND IBRUTINIB IN LINE WITH THE FRENCH MEDICAL INTERACTION THESAURUS (PUBLISHED IN MAY 2018).
PL 00057/0315	DIFLUCAN 2 MG/ML SOLUTION FOR INFUSION	GRANTED	PL 00057/0315-0106	PL 00057/0315-0106	27/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 AND 4.8 OF THE SMPC AND SECTION 2 OF THE PIL WITH INFORMATION REGARDING DRUG-DRUG INTERACTION

								WORKSHARING		BETWEEN FLUCONAZOLE AND IBRUTINIB IN LINE WITH THE FRENCH MEDICAL INTERACTION THESAURUS (PUBLISHED IN MAY 2018).
PL 00057/0317	DIFLUCAN 200MG HARD CAPSULES	GRANTED	PL 00057/0317-0124	PL 00057/0317-0124	27/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 AND 4.8 OF THE SMPC AND SECTION 2 OF THE PIL WITH INFORMATION REGARDING DRUG-DRUG INTERACTION BETWEEN FLUCONAZOLE AND IBRUTINIB IN LINE WITH THE FRENCH MEDICAL INTERACTION THESAURUS (PUBLISHED IN MAY 2018).
PL 00057/0343	DIFLUCAN 10 MG/ML POWDER FOR ORAL SUSPENSION	GRANTED	PL 00057/0343-0110	PL 00057/0343-0110	27/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 AND 4.8 OF THE SMPC AND SECTION 2 OF THE PIL WITH INFORMATION REGARDING DRUG-DRUG INTERACTION BETWEEN FLUCONAZOLE AND IBRUTINIB IN LINE WITH THE FRENCH MEDICAL INTERACTION THESAURUS

										(PUBLISHED IN MAY 2018).
PL 00057/0344	DIFLUCAN 40 MG/ML POWDER FOR ORAL SUSPENSION	GRANTED	PL 00057/0344-0109	PL 00057/0344-0109	27/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 AND 4.8 OF THE SMPC AND SECTION 2 OF THE PIL WITH INFORMATION REGARDING DRUG-DRUG INTERACTION BETWEEN FLUCONAZOLE AND IBRUTINIB IN LINE WITH THE FRENCH MEDICAL INTERACTION THESAURUS (PUBLISHED IN MAY 2018).
PL 00603/0028	NAVELBINE 10MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00603/0028-0100	PL 00603/0028-0100	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC BASED ON NEW CLINICAL DATA DISPLAYING RESULTS OF CUMULATIVE ANALYSIS ON ADVERSE EVENTS, SHOWING DISCREPANCIES BETWEEN INTRAVENOUS AND ORAL FORMS OF NAVELBINE®, IN ACCORDANCE WITH THE PRAC RECOMMENDATION PSUSA/00003124/201704 (DATED 31 OCTOBER 2018).

										AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 00603/0029	NAVELBINE 20MG SOFT CAPSULE	GRANTED	PL 00603/0029-0074	PL 00603/0029-0074	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC BASED ON NEW CLINICAL DATA DISPLAYING RESULTS OF CUMULATIVE ANALYSIS ON ADVERSE EVENTS, SHOWING DISCREPANCIES BETWEEN INTRAVENOUS AND ORAL FORMS OF NAVELBINE®, IN ACCORDANCE WITH THE PRAC RECOMMENDATION PSUSA/00003124/201704 (DATED 31 OCTOBER 2018). AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 00603/0030	NAVELBINE 30MG SOFT CAPSULE	GRANTED	PL 00603/0030-0075	PL 00603/0030-0075	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC BASED ON NEW CLINICAL DATA DISPLAYING RESULTS OF CUMULATIVE ANALYSIS ON ADVERSE EVENTS, SHOWING

										DISCREPANCIES BETWEEN INTRAVENOUS AND ORAL FORMS OF NAVELBINE®, IN ACCORDANCE WITH THE PRAC RECOMMENDATION PSUSA/00003124/201704 (DATED 31 OCTOBER 2018). AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 00603/0032	NAVELBINE 80MG SOFT CAPSULE	GRANTED	PL 00603/0032-0077	PL 00603/0032-0077	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC BASED ON NEW CLINICAL DATA DISPLAYING RESULTS OF CUMULATIVE ANALYSIS ON ADVERSE EVENTS, SHOWING DISCREPANCIES BETWEEN INTRAVENOUS AND ORAL FORMS OF NAVELBINE®, IN ACCORDANCE WITH THE PRAC RECOMMENDATION PSUSA/00003124/201704 (DATED 31 OCTOBER 2018). AS A CONSEQUENCE, THE PIL HAS BEEN

										UPDATED.
PL 08081/0040	MEZAVANT XL 1200MG, GASTRO-RESISTANT, PROLONGED RELEASE TABLETS	GRANTED	PL 08081/0040-0040	PL 08081/0040-0040	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL TO INCLUDE THE WARNING OF NEPHROLITHIASIS.
PL 08081/0040	MEZAVANT XL 1200MG, GASTRO-RESISTANT, PROLONGED RELEASE TABLETS	GRANTED	PL 08081/0040-0040	PL 08081/0040-0040	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL TO INCLUDE THE WARNING OF NEPHROLITHIASIS.
PL 13689/0005	BALANCE 1.5% GLUCOSE, 1.75 MMOL/L CALCIUM, SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0005-0039	PL 13689/0005-0039	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIES, TO INCLUDE THE SIGNAL OF ENCAPSULATING PERITONEAL SCLEROSIS (EPS). CONSEQUENTLY, IMPACTING THE PIL.
PL 13689/0006	BALANCE 4.25% GLUCOSE, 1.75 MMOL/L CALCIUM, SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0006-0041	PL 13689/0006-0041	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIES, TO INCLUDE THE SIGNAL OF ENCAPSULATING PERITONEAL SCLEROSIS (EPS). CONSEQUENTLY, IMPACTING THE PIL.

PL 13689/0007	BALANCE 2.3% GLUCOSE, 1.75 MMOL/L CALCIUM, SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0007-0042	PL 13689/0007-0042	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIES, TO INCLUDE THE SIGNAL OF ENCAPSULATING PERITONEAL SCLEROSIS (EPS). CONSEQUENTLY, IMPACTING THE PIL.
PL 13689/0011	BALANCE 1.5% GLUCOSE, 1.25 MMOL/L CALCIUM, SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0011-0040	PL 13689/0011-0040	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIES, TO INCLUDE THE SIGNAL OF ENCAPSULATING PERITONEAL SCLEROSIS (EPS). CONSEQUENTLY, IMPACTING THE PIL.
PL 13689/0012	BALANCE 4.25% GLUCOSE, 1.25 MMOL/L CALCIUM, SOLUTION FOR PERITONEAL DIALYSIS	GRANTED	PL 13689/0012-0041	PL 13689/0012-0041	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIES, TO INCLUDE THE SIGNAL OF ENCAPSULATING PERITONEAL SCLEROSIS (EPS). CONSEQUENTLY, IMPACTING THE PIL.
PL 13689/0013	BALANCE 2.3% GLUCOSE, 1.25MMOL/L CALCIUM, SOLUTION	GRANTED	PL 13689/0	PL 13689/0	31/03/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE

	FOR PERITONEAL DIALYSIS		013-0039	013-0039				(STANDARD) - CMS WORKSHARING		PHARMACOVIGILANCE SIGNAL DETECTION ACTIVITIES, TO INCLUDE THE SIGNAL OF ENCAPSULATING PERITONEAL SCLEROSIS (EPS). CONSEQUENTLY, IMPACTING THE PIL.
PL 41284/0003	DROPIZOL 10 MG/ML ORAL DROPS, SOLUTION	GRANTED	PL 41284/0003-0002	PL 41284/0003-0002	31/03/2020	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, 4.9, 5.1, 5.2 AND 5.3 OF THE SMPC ANF PIL IN AGREEMENT WITH COMMENTS RAISED DURING THE RUP VIA SEPARATE VARIATION APPLICATION WITHIN TWO MONTHS AFTER FINALISATION OF THE RUP.
PL 00057/0970	DOXORUBICIN SOLUTION FOR INJECTION 2MG/ML	GRANTED	PL 00057/0970-0022	PL 00057/0970-0022	08/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-4 AND PIL IN LINE WITH THE CCDS, SPECIFICALLY WITH REGARD TO DISCREPANCY IN THE HALF-LIFE AND WASH-OUT PERIOD OF TRASTUZUMAB.
PL 00057/1023	PHARMORUBICIN 2MG/ML SOLUTION FOR INJECTION	GRANTED	PL 00057/1023-0008	PL 00057/1023-0008	08/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-4 AND PIL IN LINE WITH THE CCDS, SPECIFICALLY WITH REGARD TO DISCREPANCY IN THE HALF-LIFE AND WASH-OUT PERIOD OF

										TRASTUZUMAB. THE MAH WILL SUBMIT THE LEAFLET MOCK-UP VIA AN ARTICLE 61(3) NOTIFICATION.
PL 00057/1060	ZAVEDOS 10MG POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/1060-0019	PL 00057/1060-0019	08/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-4 AND PIL IN LINE WITH THE CCDS, SPECIFICALLY WITH REGARD TO DISCREPANCY IN THE HALF-LIFE AND WASH-OUT PERIOD OF TRASTUZUMAB.
PL 00057/1061	ZAVEDOS 5MG POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/1061-0017	PL 00057/1061-0017	08/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-4 AND PIL IN LINE WITH THE CCDS, SPECIFICALLY WITH REGARD TO DISCREPANCY IN THE HALF-LIFE AND WASH-OUT PERIOD OF TRASTUZUMAB.
PL 00057/1062	ZAVEDOS CAPSULES 10MG	GRANTED	PL 00057/1062-0020	PL 00057/1062-0020	08/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-4 AND PIL IN LINE WITH THE CCDS, SPECIFICALLY WITH REGARD TO DISCREPANCY IN THE HALF-LIFE AND WASH-OUT PERIOD OF TRASTUZUMAB.
PL 00057/1064	ZAVEDOS CAPSULES 5MG	GRANTED	PL 00057/1064-0020	PL 00057/1064-0020	08/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC 4-4 AND PIL IN LINE WITH THE CCDS, SPECIFICALLY WITH REGARD TO DISCREPANCY IN THE HALF-LIFE AND WASH-

								WORKSHARING		OUT PERIOD OF TRASTUZUMAB.
PL 00057/1520	ZAVEDOS 1 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 00057/1520-0005	PL 00057/1520-0005	08/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC 4-4 AND PIL IN LINE WITH THE CCDS, SPECIFICALLY WITH REGARD TO DISCREPANCY IN THE HALF-LIFE AND WASH-OUT PERIOD OF TRASTUZUMAB.
PL 00242/0142	SPORANOX 100MG CAPSULES	GRANTED	PL 00242/0142-0150	PL 00242/0142-0150	14/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.5 OF THE SMPC TO INCLUDE THE MOST RECENT DRUG INTERACTIONS INVOLVING ITRACONAZOLE. [2] TO UPDATE SECTION 4.9 OF THE SMPC IN LINE WITH THE CCDS TO REMOVE ACTIVATED CHARCOAL (ORAL SOLUTION ONLY) AND TO ADD A STATEMENT TO CONTACT A POISON CONTROL CENTRE FOR THE LATEST RECOMMENDATIONS FOR MANAGEMENT OF AN OVERDOSE (ORAL SOLUTION AND IV). [3] TO UPDATE SECTION 5.3 OF THE

										SMPC IN LINE WITH THE CCDS TO ADD FURTHER DETAIL ON SPECIFIC DOSES USED IN ANIMAL TOXICITY STUDIES AND DOSES STUDIED FOR CARCINOGENICITY AND MUTAGENICITY, THE ADDITION OF INFORMATION ON REPRODUCTIVE TOXICITY. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL AND PACKAGE LABELLING HAVE BEEN UPDATED.
PL 00242/0307	SPORANOX 10 MG/ML ORAL SOLUTION	GRANTED	PL 00242/0307-0106	PL 00242/0307-0106	14/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.5 OF THE SMPC TO INCLUDE THE MOST RECENT DRUG INTERACTIONS INVOLVING ITRACONAZOLE. [2] TO UPDATE SECTION 4.9 OF THE SMPC IN LINE WITH THE CCDS TO REMOVE ACTIVATED

										CHARCOAL (ORAL SOLUTION ONLY) AND TO ADD A STATEMENT TO CONTACT A POISON CONTROL CENTRE FOR THE LATEST RECOMMENDATIONS FOR MANAGEMENT OF AN OVERDOSE (ORAL SOLUTION AND IV). [3] TO UPDATE SECTION 5.3 OF THE SMPC IN LINE WITH THE CCDS TO ADD FURTHER DETAIL ON SPECIFIC DOSES USED IN ANIMAL TOXICITY STUDIES AND DOSES STUDIED FOR CARCINOGENICITY AND MUTAGENICITY, THE ADDITION OF INFORMATION ON REPRODUCTIVE TOXICITY. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL AND PACKAGE

										LABELLING HAVE BEEN UPDATED.
PL 00242/0334	SPORANOX - PULSE	GRANTED	PL 00242/0334-0122	PL 00242/0334-0122	14/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.5 OF THE SMPC TO INCLUDE THE MOST RECENT DRUG INTERACTIONS INVOLVING ITRACONAZOLE. [2] TO UPDATE SECTION 4.9 OF THE SMPC IN LINE WITH THE CCDS TO REMOVE ACTIVATED CHARCOAL (ORAL SOLUTION ONLY) AND TO ADD A STATEMENT TO CONTACT A POISON CONTROL CENTRE FOR THE LATEST RECOMMENDATIONS FOR MANAGEMENT OF AN OVERDOSE (ORAL SOLUTION AND IV). [3] TO UPDATE SECTION 5.3 OF THE SMPC IN LINE WITH THE CCDS TO ADD FURTHER DETAIL ON SPECIFIC DOSES USED IN ANIMAL TOXICITY STUDIES AND DOSES STUDIED FOR CARCINOGENICITY

										AND MUTAGENICITY, THE ADDITION OF INFORMATION ON REPRODUCTIVE TOXICITY. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL AND PACKAGE LABELLING HAVE BEEN UPDATED.
PL 00242/0345	0.9% SODIUM CHLORIDE INJECTION	GRANTED	PL 00242/0345-0080	PL 00242/0345-0080	14/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.5 OF THE SMPC TO INCLUDE THE MOST RECENT DRUG INTERACTIONS INVOLVING ITRACONAZOLE. [2] TO UPDATE SECTION 4.9 OF THE SMPC IN LINE WITH THE CCDS TO REMOVE ACTIVATED CHARCOAL (ORAL SOLUTION ONLY) AND TO ADD A STATEMENT TO CONTACT A POISON CONTROL CENTRE FOR THE LATEST RECOMMENDATIONS FOR MANAGEMENT OF

										AN OVERDOSE (ORAL SOLUTION AND IV). [3] TO UPDATE SECTION 5.3 OF THE SMPC IN LINE WITH THE CCDS TO ADD FURTHER DETAIL ON SPECIFIC DOSES USED IN ANIMAL TOXICITY STUDIES AND DOSES STUDIED FOR CARCINOGENICITY AND MUTAGENICITY, THE ADDITION OF INFORMATION ON REPRODUCTIVE TOXICITY. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL AND PACKAGE LABELLING HAVE BEEN UPDATED.
PL 14434/0017	NORADRENALINE (NOREPINEPHRINE) 1 MG / ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 14434/0017-0037	PL 14434/0017-0037	15/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO ADD A NEW ADVERSE EFFECT (GANGRENE OF THE EXTREMITIES - SOC: VASCULAR DISORDERS)IN SECTION 4.8 OF THE SMPC AND SECTION 2

										OF THE PIL OF NORADRENALINE (NOREPINEPHRINE) 1 MG / ML CONCENTRATE FOR SOLUTION FOR INFUSION.
PL 01502/0059	MIDAZOLAM 1MG/ML, SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 01502/0059-0054	PL 01502/0059-0054	20/04/2020	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, 5.1 AND 5.2 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT HYPNOVEL 10MG/2ML SOLUTION FOR INJECTION AND IN LINE WITH THE QRD TEMPLATE.
PL 01502/0060	MIDAZOLAM 2MG/ML, SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 01502/0060-0051	PL 01502/0060-0051	20/04/2020	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, 5.1 AND 5.2 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT HYPNOVEL 10MG/2ML SOLUTION FOR INJECTION AND IN LINE WITH THE QRD TEMPLATE.
PL 01502/0061	MIDAZOLAM 5MG/ML, SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 01502/0061-0056	PL 01502/0061-0056	20/04/2020	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, 5.1 AND 5.2 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT HYPNOVEL 10MG/2ML SOLUTION FOR INJECTION AND

										IN LINE WITH THE QRD TEMPLATE.
PL 04416/0668	AZITHROMYCIN 500MG TABLETS	GRANTED	PL 04416/0668-0059	PL 04416/0668-0059	21/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.7, 4.8, 4.9 AND 10 OF THE SPC FOR EFERENCE PRODUCT ZITHROMAX 250, TABLETTEN 250 MG/ZITHROMAX 500, TABLETTEN 500 MG, PFIZER BV, RVG 19432/ RVG 19432, MAY 2019. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED
PL 04416/0782	AZITHROMYCIN 200MG/5ML POWDER FOR ORAL SUSPENSION	GRANTED	PL 04416/0782-0051	PL 04416/0782-0051	21/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.7, 4.8, 4.9 AND 10 OF THE SPC TO THE NOT HARMONISED REFERENCE PRODUCT ZITHROMAX, SUSPENSIE (POEDER VOOR) 200 MG/5 ML, PFIZER BV, RVG 14999, MAY 2019. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 00093/0024	DIAMICRON 80 MG TABLETS	GRANTED	PL 00093/0024-0077	PL 00093/0024-0077	23/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC TO ADD A WARNING RELATED TO THE RISK OF ACUTE PORPHYRIA, AS CLASS EFFECT IN PATIENTS WHO HAVE

										PORPHYRIA AND TO ADD 'AUTOIMMUNE BULLOUS DISORDERS' AS UNDESIRABLE EFFECTS. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 05815/0019	DIAMICRON 30MG MR TABLETS	GRANTED	PL 05815/0019-0083	PL 05815/0019-0083	23/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC TO ADD A WARNING RELATED TO THE RISK OF ACUTE PORPHYRIA, AS CLASS EFFECT IN PATIENTS WHO HAVE PORPHYRIA AND TO ADD 'AUTOIMMUNE BULLOUS DISORDERS' AS UNDESIRABLE EFFECTS. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04416/1318	ACCRETE D3 ONE A DAY 1000 MG/880 IU CHEWABLE TABLETS	GRANTED	PL 04416/1318-0030	PL 04416/1318-0030	26/04/2020	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 AND 4.9 AND PIL TO INCLUDE IMPORTANT NEW SAFETY AND EFFICACY INFORMATION ASSOCIATED WITH CALCIUM CARBONATE/COLECALCIFEROL COMBINATION AS

										WELL AS WITH CALCIUM CARBONATE OR COLECALCIFEROL ALONE PUBLISHED SINCE LAST APPROVED SMPC.
PL 15513/0377	BENYLIN MUCUS COUGH MAX HONEY & LEMON FLAVOUR 100 MG/5 ML SYRUP	GRANTED	PL 15513/0377-0036	PL 15513/0377-0036	28/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO UPDATE SECTIONS 2 AND 4.4 OF THE SMPC TO REFLECT POST RENEWAL REQUESTS, EXCIPIENT LABELING UPDATES AND QRD UPDATES. 2.TO REGISTRATION OF A NEW LITERATURE REFERENCE ALBRECHT ET AL. 2017 TO SUPPORT THE CLINICAL OVERVIEW
PL 15513/0377	BENYLIN MUCUS COUGH MAX HONEY & LEMON FLAVOUR 100 MG/5 ML SYRUP	GRANTED	PL 15513/0377-0036	PL 15513/0377-0036	28/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO UPDATE SECTIONS 2 AND 4.4 OF THE SMPC TO REFLECT POST RENEWAL REQUESTS, EXCIPIENT LABELING UPDATES AND QRD UPDATES. 2.TO REGISTRATION OF A NEW LITERATURE REFERENCE ALBRECHT ET AL. 2017

										TO SUPPORT THE CLINICAL OVERVIEW
PL 44673/0118	NICOTINELL MINT 1MG COMPRESSED LOZENGES	GRANTED	PL 44673/0118-0025	PL 44673/0118-0025	29/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH THE GLOBAL SAFETY INFORMATION FOR ALL NICOTINE LOZENGE MARKETING AUTHORISATIONS. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 44673/0118	NICOTINELL MINT 1MG COMPRESSED LOZENGES	GRANTED	PL 44673/0118-0025	PL 44673/0118-0025	29/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH THE GLOBAL SAFETY INFORMATION FOR ALL NICOTINE LOZENGE MARKETING AUTHORISATIONS. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 44673/0119	NICOTINELL MINT 2MG COMPRESSED LOZENGES	GRANTED	PL 44673/0119-0022	PL 44673/0119-0022	29/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH THE GLOBAL SAFETY INFORMATION FOR ALL NICOTINE LOZENGE MARKETING AUTHORISATIONS. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 44673/0119	NICOTINELL MINT 2MG COMPRESSED LOZENGES	GRANTED	PL 44673/0119-0022	PL 44673/0119-0022	29/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH THE GLOBAL SAFETY INFORMATION FOR ALL NICOTINE LOZENGE MARKETING AUTHORISATIONS. ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04854/0158	LEVOSERT 20 MICROGRAM/24	GRANTED	PL 04854/0	PL 04854/0	30/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.2,4.4, 4.8, 5.1 AND 5.2 OF THE SMPC AND

	HOURS INTRAUTERINE DELIVERY SYSTEM		158-0029	158-0029				(STANDARD) - CMS		PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA (6 YEARS TREATMENT DURATION).
PL 04854/0158	LEVOSERT 20 MICROGRAM/24 HOURS INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 04854/0158-0030	PL 04854/0158-0030	30/04/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE RMP AS THE CONSEQUENCE OF PSUFU ASSESSMENT REPORT FOR THE LNG IUS
PL 16950/0157	TARGINACT 10 MG/5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 16950/0157-0086	PL 16950/0157-0086	01/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN ACCORDANCE PSUSA SAFETY SIGNAL CONCERNING THE RISK OF THE INTERACTION BETWEEN OXYCODONE AND SEROTONERGIC DRUGS, LEADING TO SEROTONIN SYNDROME AND ADDED SAFETY UPDATE CONCERNING RISK OF CONCOMITANT TREATMENT WITH GABAPENTINOIDS SUCH AS PREGABALIN AND THE INCREASED RISK OF CNS DEPRESSION.

PL 16950/0158	TARGINACT 20 MG/10 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 16950/0158-0085	PL 16950/0158-0085	01/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN ACCORDANCE PSUSA SAFETY SIGNAL CONCERNING THE RISK OF THE INTERACTION BETWEEN OXYCODONE AND SEROTONERGIC DRUGS, LEADING TO SEROTONIN SYNDROME AND ADDED SAFETY UPDATE CONCERNING RISK OF CONCOMITANT TREATMENT WITH GABAPENTINOIDS SUCH AS PREGABALIN AND THE INCREASED RISK OF CNS DEPRESSION.
PL 16950/0161	TARGINACT 40 MG/20 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 16950/0161-0082	PL 16950/0161-0082	01/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN ACCORDANCE PSUSA SAFETY SIGNAL CONCERNING THE RISK OF THE INTERACTION BETWEEN OXYCODONE AND SEROTONERGIC DRUGS, LEADING TO SEROTONIN SYNDROME AND ADDED SAFETY UPDATE CONCERNING RISK OF

										CONCOMITANT TREATMENT WITH GABAPENTINOIDS SUCH AS PREGABALIN AND THE INCREASED RISK OF CNS DEPRESSION.
PL 16950/0162	TARGINACT 5 MG/2.5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 16950/0162-0086	PL 16950/0162-0086	01/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN ACCORDANCE PSUSA SAFETY SIGNAL CONCERNING THE RISK OF THE INTERACTION BETWEEN OXYCODONE AND SEROTONERGIC DRUGS, LEADING TO SEROTONIN SYNDROME AND ADDED SAFETY UPDATE CONCERNING RISK OF CONCOMITANT TREATMENT WITH GABAPENTINOIDS SUCH AS PREGABALIN AND THE INCREASED RISK OF CNS DEPRESSION.
PL 04569/1060	PERINDOPRIL ARGININE / INDAPAMIDE 5 MG/1.25 MG FILM-COATED TABLETS	GRANTED	PL 04569/1060-0020	PL 04569/1060-0020	04/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.3, 4.4 AND 4.5 OF THE SMPC DUE TO NEW CLINICAL DATA - AN INTERNAL SAFETY SIGNAL ON A DRUG INTERACTION OF GENERIC ACE INHIBITORS AND

										NEPRILYS INHIBITORS RESULTING IN AN INCREASED RISK OF ANGIOEDEMA. ADDITIONALLY, UPDATES HAVE BEEN MADE IN LINE WITH THE EXCIPIENTS GUIDELINE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 17901/0038	SEROQUEL 25 MG FILM-COATED TABLETS	GRANTED	PL 17901/0038-0205	PL 17901/0038-0205	04/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND SECTION 2 AND 4 PIL TO INCLUDE DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS). ADDITIONALLY THE PI HAS BEEN UPDATED IN LINE WITH THE QRD TEMPLATE AND IN LINE WITH ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON 'EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE.
PL 17901/0039	SEROQUEL 100 MG FILM-COATED TABLETS	GRANTED	PL 17901/0	PL 17901/0	04/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND SECTION 2 AND 4 PIL

			039-0202	039-0202				(STANDARD) - CMS		TO INCLUDE DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS). ADDITIONALLY THE PI HAS BEEN UPDATED IN LINE WITH THE QRD TEMPLATE AND IN LINE WITH ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON 'EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE.
PL 17901/0040	SEROQUEL 200 MG FILM-COATED TABLETS	GRANTED	PL 17901/0040-0200	PL 17901/0040-0200	04/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND SECTION 2 AND 4 PIL TO INCLUDE DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS). ADDITIONALLY THE PI HAS BEEN UPDATED IN LINE WITH THE QRD TEMPLATE AND IN LINE WITH ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON 'EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL

										PRODUCTS FOR HUMAN USE.
PL 17901/0088	SEROQUEL 300 MG FILM-COATED TABLETS	GRANTED	PL 17901/0088-0199	PL 17901/0088-0199	04/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND SECTION 2 AND 4 PIL TO INCLUDE DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS). ADDITIONALLY THE PI HAS BEEN UPDATED IN LINE WITH THE QRD TEMPLATE AND IN LINE WITH ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON 'EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE.
PL 17901/0249	SEROQUEL XL 50 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17901/0249-0150	PL 17901/0249-0150	04/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.4 OF THE SPC TO INCLUDE DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS) AND TO INCLUDE SJS/TENS. 2) TO UPDATE SECTIONS 4.8 AND 4.9 OF THE SPC BASED ON A REVIEW OF ALL CURRENTLY

										AVAILABLE INFORMATION, IN PARTICULAR SPONTANEOUS REPORTS, QUANTITATIVE SCORES (EVDAS, FAERS, WHO VIGIBASE AND NGSMS), BIOLOGICPHARMACOLOGIC PLAUSIBILITY AND MECHANISTIC ASSOCIATION IN SCIENTIFIC LITERATURE ALIGNED WITH SAGE SCORING. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 17901/0250	SEROQUEL XL 200 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17901/0250-0150	PL 17901/0250-0150	04/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.4 OF THE SPC TO INCLUDE DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS) AND TO INCLUDE SJS/TENS. 2) TO UPDATE SECTIONS 4.8 AND 4.9 OF THE SPC BASED ON A REVIEW OF ALL CURRENTLY AVAILABLE INFORMATION, IN PARTICULAR SPONTANEOUS REPORTS,

										QUANTITATIVE SCORES (EVDAS, FAERS, WHO VIGIBASE AND NGSMS), BIOLOGICPHARMACOLOGIC PLAUSIBILITY AND MECHANISTIC ASSOCIATION IN SCIENTIFIC LITERATURE ALIGNED WITH SAGE SCORING. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 17901/0251	SEROQUEL XL 300 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17901/0251-0148	PL 17901/0251-0148	04/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.4 OF THE SPC TO INCLUDE DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS) AND TO INCLUDE SJS/TENS. 2) TO UPDATE SECTIONS 4.8 AND 4.9 OF THE SPC BASED ON A REVIEW OF ALL CURRENTLY AVAILABLE INFORMATION, IN PARTICULAR SPONTANEOUS REPORTS, QUANTITATIVE SCORES (EVDAS, FAERS, WHO VIGIBASE AND NGSMS), BIOLOGICPHARMACOL

										OGIC PLAUSIBILITY AND MECHANISTIC ASSOCIATION IN SCIENTIFIC LITERATURE ALIGNED WITH SAGE SCORING. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 17901/0252	SEROQUEL XL 400 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17901/0252-0150	PL 17901/0252-0150	04/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.4 OF THE SPC TO INCLUDE DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS) AND TO INCLUDE SJS/TENS. 2) TO UPDATE SECTIONS 4.8 AND 4.9 OF THE SPC BASED ON A REVIEW OF ALL CURRENTLY AVAILABLE INFORMATION, IN PARTICULAR SPONTANEOUS REPORTS, QUANTITATIVE SCORES (EVDAS, FAERS, WHO VIGIBASE AND NGSMS), BIOLOGICPHARMACOLOGIC PLAUSIBILITY AND MECHANISTIC ASSOCIATION IN SCIENTIFIC LITERATURE ALIGNED

										WITH SAGE SCORING. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 17901/0259	SEROQUEL XL 150MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17901/0259-0114	PL 17901/0259-0114	04/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.4 OF THE SPC TO INCLUDE DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS) AND TO INCLUDE SJS/TENS. 2) TO UPDATE SECTIONS 4.8 AND 4.9 OF THE SPC BASED ON A REVIEW OF ALL CURRENTLY AVAILABLE INFORMATION, IN PARTICULAR SPONTANEOUS REPORTS, QUANTITATIVE SCORES (EVDAS, FAERS, WHO VIGIBASE AND NGSMS), BIOLOGICPHARMACOLOGIC PLAUSIBILITY AND MECHANISTIC ASSOCIATION IN SCIENTIFIC LITERATURE ALIGNED WITH SAGE SCORING. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 33016/0008	BALNEUM	GRANTED	PL 33016/0008-0030	PL 33016/0008-0030	06/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO ADD DETAILS OF A RISK ASSESSMENT TO PROVIDE AN ASSESSMENT OF THE AMOUNT OF OLEIC ACID DIETHANOLAMIDE IN THE CONCERNED MEDICINAL PRODUCTS AS WELL AS TO IDENTIFY THE LEVEL OF CONTAMINATION WITH DIETHANOLAMINE AND TO PROVIDE INFORMATION REGARDING THE POTENTIAL CONTAMINATION AND FORMATION OF NITROSAMINES AFTER APPLICATION OF THE MEDICINAL PRODUCT. THIS VARIATION IS SUBMITTED UNDER WORKSHARING PROCEDURE ACCORDING TO ARTICLE 20 OF COMMISSION REGULATION (EC) NO 1234/2008 OF 24 NOVEMBER 2008 AS AMENDED BY COMMISSION REGULATION (EU) NO

										712/2012 OF 3 AUGUST 2012, AND COVERS PURELY NATIONAL MARKETING AUTHORISATIONS FROM THE SAME MARKETING AUTHORISATION HOLDER AS DEFINED IN THE COMMISSION COMMUNICATION 98/C 229/03.
PL 33016/0008	SOYA OIL 84.75 % W/W BATH ADDITIVE	GRANTED	PL 33016/0008-0030	PL 33016/0008-0030	06/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO ADD DETAILS OF A RISK ASSESSMENT TO PROVIDE AN ASSESSMENT OF THE AMOUNT OF OLEIC ACID DIETHANOLAMIDE IN THE CONCERNED MEDICINAL PRODUCTS AS WELL AS TO IDENTIFY THE LEVEL OF CONTAMINATION WITH DIETHANOLAMINE AND TO PROVIDE INFORMATION REGARDING THE POTENTIAL CONTAMINATION AND FORMATION OF NITROSAMINES AFTER APPLICATION OF THE MEDICINAL PRODUCT. THIS VARIATION IS

										SUBMITTED UNDER WORKSHARING PROCEDURE ACCORDING TO ARTICLE 20 OF COMMISSION REGULATION (EC) NO 1234/2008 OF 24 NOVEMBER 2008 AS AMENDED BY COMMISSION REGULATION (EU) NO 712/2012 OF 3 AUGUST 2012, AND COVERS PURELY NATIONAL MARKETING AUTHORISATIONS FROM THE SAME MARKETING AUTHORISATION HOLDER AS DEFINED IN THE COMMISSION COMMUNICATION 98/C 229/03.
PL 31750/0055	FYREMADEL 0.25 MG/0.5 ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 31750/0055-0019	PL 31750/0055-0019	06/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REQUEST THE ADDITION OF A RISK MANAGEMENT PLAN FOR FYREMADEL,TO ENSURE COMPLIANCE WITH CURRENT REGULATORY REQUIREMENTS.
PL 11587/0059	TOPOTECAN MEDAC 1 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 11587/0059-0026	PL 11587/0059-0026	12/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2 AND 4.8 OF THE SMPC IN LINE WITH PRODUCT INFORMATION TEXTS WITH THE LATEST QRD TEMPLATE.

PL 04425/0638	TILDIEM LA 300MG PROLONGED-RELEASE CAPSULES, HARD	GRANTED	PL 04425/0638-0051	PL 04425/0638-0051	13/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC BY ADDING A NEW INFORMATION CONCERNING "CASES OF ACUTE RENAL FAILURE SECONDARY TO DECREASED RENAL PERFUSION REPORTED IN PATIENTS WITH REDUCED LEFT VENTRICULAR FUNCTION, SEVERE BRADYCARDIA OR SEVERE HYPOTENSION". THE PACKAGE LEAFLET (PL) IS IMPACTED IN SECTION 2, IN SUB-SECTION "WARNINGS AND PRECAUTIONS". THE SMPC AND PACKAGE LEAFLET HAVE ALSO BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE VERSION 10.1.
PL 04425/0639	TILDIEM LA 200MG PROLONGED-RELEASE CAPSULES, HARD	GRANTED	PL 04425/0639-0051	PL 04425/0639-0051	13/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC BY ADDING A NEW INFORMATION CONCERNING "CASES OF ACUTE RENAL FAILURE SECONDARY TO DECREASED RENAL PERFUSION

										REPORTED IN PATIENTS WITH REDUCED LEFT VENTRICULAR FUNCTION, SEVERE BRADYCARDIA OR SEVERE HYPOTENSION". THE PACKAGE LEAFLET (PL) IS IMPACTED IN SECTION 2, IN SUB-SECTION "WARNINGS AND PRECAUTIONS". THE SMPC AND PACKAGE LEAFLET HAVE ALSO BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE VERSION 10.1.
PL 04425/0640	TILDIEM 60MG MODIFIED-RELEASE TABLETS	GRANTED	PL 04425/0640-0067	PL 04425/0640-0067	13/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC BY ADDING A NEW INFORMATION CONCERNING "CASES OF ACUTE RENAL FAILURE SECONDARY TO DECREASED RENAL PERFUSION REPORTED IN PATIENTS WITH REDUCED LEFT VENTRICULAR FUNCTION, SEVERE BRADYCARDIA OR SEVERE HYPOTENSION". THE PACKAGE LEAFLET

										(PL) IS IMPACTED IN SECTION 2, IN SUB-SECTION "WARNINGS AND PRECAUTIONS". THE SMPC AND PACKAGE LEAFLET HAVE ALSO BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE VERSION 10.1.
PL 04425/0641	TILDIEM RETARD 90MG PROLONGED-RELEASE TABLETS	GRANTED	PL 04425/0641-0066	PL 04425/0641-0066	13/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC BY ADDING A NEW INFORMATION CONCERNING "CASES OF ACUTE RENAL FAILURE SECONDARY TO DECREASED RENAL PERFUSION REPORTED IN PATIENTS WITH REDUCED LEFT VENTRICULAR FUNCTION, SEVERE BRADYCARDIA OR SEVERE HYPOTENSION". THE PACKAGE LEAFLET (PL) IS IMPACTED IN SECTION 2, IN SUB-SECTION "WARNINGS AND PRECAUTIONS". THE SMPC AND PACKAGE LEAFLET HAVE ALSO BEEN UPDATED IN LINE

										WITH THE LATEST QRD TEMPLATE VERSION 10.1.
PL 04425/0642	TILDIEM RETARD 120MG PROLONGED-RELASE TABLETS	GRANTED	PL 04425/0642-0061	PL 04425/0642-0061	13/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC BY ADDING A NEW INFORMATION CONCERNING "CASES OF ACUTE RENAL FAILURE SECONDARY TO DECREASED RENAL PERFUSION REPORTED IN PATIENTS WITH REDUCED LEFT VENTRICULAR FUNCTION, SEVERE BRADYCARDIA OR SEVERE HYPOTENSION". THE PACKAGE LEAFLET (PL) IS IMPACTED IN SECTION 2, IN SUB-SECTION "WARNINGS AND PRECAUTIONS". THE SMPC AND PACKAGE LEAFLET HAVE ALSO BEEN UPDATED IN LINE WITH THE LATEST QRD TEMPLATE VERSION 10.1.
PL 00010/0549	NEBIDO 1000MG/4ML, SOLUTION FOR INJECTION	GRANTED	PL 00010/0549-0060	PL 00010/0549-0060	14/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE VERSION OF EUROPEAN RISK MANAGEMENT PLAN (EU-RMP) COVERING THE NEBIDO LICENCES

								WORKSHARING		AUTHORISED VIA MRP NO (FI/H/313/01/MR) AND NATIONAL PROCEDURES (NPS).
PL 04416/0703	COLIXIL XL 4 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 04416/0703-0053	PL 04416/0703-0053	14/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 2, 3, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.1, 6.5 AND 6.6 OF THE SMPC AND PIL TO ADOPT TO THE NOT HARMONISED REFERENCE PRODUCT CARDURA XL 4, TABLETTEN MET GEREGULEERDE AFGIFTE 4 MG, PFIZER B.V, JULY 2018
PL 00289/2255	COLOMYCIN INJECTION 1 MILLION INTERNATIONAL UNITS. POWDER FOR SOLN FOR INJ, INFUSION OR INHALATION	GRANTED	PL 00289/2255-0013	PL 00289/2255-0013	15/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2,4.4,4.6, 4.8,5.1 AND 6.1 OF THE SMPC AND PIL DUE TO AN ISSUE AS RAISED AT THE RECENT CMDH MEETING HELD IN APRIL 2019, WHERE IT WAS HIGHLIGHTED THAT THE PRODUCT INFORMATION FOR THE PRODUCT, COLOMYCIN 1 MILLION AND 2 MILLION IU POWDER FOR SOLUTION FOR INJECTION, INFUSION OR INHALATION, DID NOT CONTAIN ANY REFERENCE TO THE RECOMMENDED NEBULISERS IN LINE

										WITH THE GUIDELINE ON THE PHARMACEUTICAL QUALITY OF INHALATION AND NASAL PRODUCTS EMEA/CHMP/QWP/49313/2005.
PL 00289/2256	COLOMYCIN INJECTION 2 MILLION INTERNATIONAL UNITS. POWDER FOR SOLN FOR INJ, INFUSION OR INHALATION	GRANTED	PL 00289/2256-0013	PL 00289/2256-0013	15/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2,4.4,4.6, 4.8,5.1 AND 6.1 OF THE SMPC AND PIL DUE TO AN ISSUE AS RAISED AT THE RECENT CMDH MEETING HELD IN APRIL 2019, WHERE IT WAS HIGHLIGHTED THAT THE PRODUCT INFORMATION FOR THE PRODUCT, COLOMYCIN 1 MILLION AND 2 MILLION IU POWDER FOR SOLUTION FOR INJECTION, INFUSION OR INHALATION, DID NOT CONTAIN ANY REFERENCE TO THE RECOMMENDED NEBULISERS IN LINE WITH THE GUIDELINE ON THE PHARMACEUTICAL QUALITY OF INHALATION AND NASAL PRODUCTS EMEA/CHMP/QWP/49313/2005.

PL 18920/0039	MULTIHANCE 0.5M SOLUTION FOR INJECTION	GRANTED	PL 18920/0039-0008	PL 18920/0039-0008	15/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND PIL OF MULTIHANCE (BOTH VIAL AND PREFILLED PRESENTATION) TO THE CORRESPONDING SECTION OF THE CURRENT COMPANY CORE SAFETY INFORMATION (CSI), DATED 29 APRIL 2019.
PL 18920/0040	MULTIHANCE 529 MG/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 18920/0040-0008	PL 18920/0040-0008	15/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND PIL OF MULTIHANCE (BOTH VIAL AND PREFILLED PRESENTATION) TO THE CORRESPONDING SECTION OF THE CURRENT COMPANY CORE SAFETY INFORMATION (CSI), DATED 29 APRIL 2019.
PL 00038/0270	AUGMENTIN 375MG TABLETS	GRANTED	PL 00038/0270-0144	PL 00038/0270-0144	17/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REGISTER VERSION 2.4 OF THE EU-RISK MANAGEMENT PLAN (RMP).
PL 00038/0320	AUGMENTIN INTRAVENOUS 600MG AND AUGMENTIN INTRAVENOUS 1.2 G	GRANTED	PL 00038/0320-0141	PL 00038/0320-0141	17/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER VERSION 2.4 OF THE EU-RISK MANAGEMENT PLAN (RMP).

								WORKSHARING		
PL 00038/0362	AUGMENTIN 625MG TABLETS	GRANTED	PL 00038/0362-0151	PL 00038/0362-0151	17/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REGISTER VERSION 2.4 OF THE EU-RISK MANAGEMENT PLAN (RMP).
PL 10592/0070	AUGMENTIN 400/57	GRANTED	PL 10592/0070-0120	PL 10592/0070-0120	17/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REGISTER VERSION 2.4 OF THE EU-RISK MANAGEMENT PLAN (RMP).
PL 00025/0357	SINGULAIR PAEDIATRIC 5MG CHEWABLE TABLETS	GRANTED	PL 00025/0357-0107	PL 00025/0357-0107	18/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL ACCORDING TO SECTION VI. PREGNANCY OF THE COMPANY CORE DATA SHEET (CCDS) FOR SINGULAIR (MONTELUKAST SODIUM).
PL 00025/0358	SINGULAIR 10MG FILM-COATED TABLET	GRANTED	PL 00025/0358-0103	PL 00025/0358-0103	18/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL ACCORDING TO SECTION VI. PREGNANCY OF THE COMPANY CORE DATA SHEET (CCDS) FOR SINGULAIR (MONTELUKAST SODIUM).

PL 00025/0412	SINGULAIRÂ® PAEDIATRIC 4MG CHEWABLE TABLETS	GRANTED	PL 00025/0412-0098	PL 00025/0412-0098	18/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL ACCORDING TO SECTION VI. PREGNANCY OF THE COMPANY CORE DATA SHEET (CCDS) FOR SINGULAIR (MONTELUKAST SODIUM).
PL 00025/0412	SINGULAIR PAEDIATRIC 4MG CHEWABLE TABLETS	GRANTED	PL 00025/0412-0098	PL 00025/0412-0098	18/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL ACCORDING TO SECTION VI. PREGNANCY OF THE COMPANY CORE DATA SHEET (CCDS) FOR SINGULAIR (MONTELUKAST SODIUM).
PL 00025/0440	SINGULAIR PAEDIATRIC 4MG GRANULES	GRANTED	PL 00025/0440-0100	PL 00025/0440-0100	18/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL ACCORDING TO SECTION VI. PREGNANCY OF THE COMPANY CORE DATA SHEET (CCDS) FOR SINGULAIR (MONTELUKAST SODIUM).
PL 45496/0009	BELKYRA 10 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 45496/0009-0012	PL 45496/0009-0012	20/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL TO REFLECT THE LATEST SAFETY INFORMATION WITHIN THE COMPANY CORE DATA SHEET (CCDS).

PL 20075/1369	PIPERACILLIN/TAZOBACTAM 4 G/0.5 G POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 20075/1369-0005	PL 20075/1369-0005	27/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE SMPC AND PIL INFORMATION 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: UK/H/4984/001-002 AND MAH: PFIZER LIMITED) FOR PIPERACILLIN/TAZOBACTAM 2 G/0.25 G AND 4 G/0.5 G POWDER FOR SOLUTION FOR INFUSION. CONSEQUENTLY, SECTIONS 4.1 AND 4.8 OF THE SMPC HAVE BEEN UPDATED.
PL 17901/0099	ATACAND 16MG TABLETS	GRANTED	PL 17901/0099-0107	PL 17901/0099-0107	28/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FROM VERSIONS 1.3 (CANDESARTAN, DATED 19 JULY 2013) AND 4.0 (CANDESARTAN + HCT, DATED 15 NOVEMBER 2017) TO VERSION 2.0

										(26 JUNE 2019) (COMBINED).
PL 17901/0101	ATACAND 4MG TABLETS	GRANTED	PL 17901/0101-0110	PL 17901/0101-0110	28/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FROM VERSIONS 1.3 (CANDESARTAN, DATED 19 JULY 2013) AND 4.0 (CANDESARTAN + HCT, DATED 15 NOVEMBER 2017) TO VERSION 2.0 (26 JUNE 2019) (COMBINED).
PL 17901/0102	ATACAND 8MG TABLETS	GRANTED	PL 17901/0102-0109	PL 17901/0102-0109	28/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FROM VERSIONS 1.3 (CANDESARTAN, DATED 19 JULY 2013) AND 4.0 (CANDESARTAN + HCT, DATED 15 NOVEMBER 2017) TO VERSION 2.0 (26 JUNE 2019) (COMBINED).
PL 17901/0210	ATACAND 32MG TABLETS	GRANTED	PL 17901/0210-0091	PL 17901/0210-0091	28/05/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FROM VERSIONS 1.3 (CANDESARTAN, DATED

								WORKSHARING		19 JULY 2013) AND 4.0 (CANDESARTAN + HCT, DATED 15 NOVEMBER 2017) TO VERSION 2.0 (26 JUNE 2019) (COMBINED).
PL 10921/0023	COPAXONE 20MG/ML SOLUTION FOR INJECTION, PREFILLED SYRINGE	GRANTED	PL 10921/0023-0199	PL 10921/0023-0199	02/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO SUBMIT AN UPDATED RMP TO INCLUDE THE AMENDED SAFETY INFORMATION AND THE COLLECTION OF DETAILED INFORMATION ON PREGNANCY CASES IN THE EU AS ROUTINE PHARMACOVIGILANCE ACTIVITY.¿
PL 04569/0898	FINASTERIDE 1MG FILM-COATED TABLETS	GRANTED	PL 04569/0898-0050	PL 04569/0898-0050	03/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 AND 5.1 OF THE SMPC FRAGMENTS IN LINE WITH THE REFERENCE PRODUCT FROM THE ORIGINAL APPLICATION, PROPECIA, MERCK SHARP & DOHME BV SE/H/0158/001. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 08829/0155	BRAMITOB 300MG/4ML NEBULISER SOLUTION	GRANTED	PL 08829/0155-0064	PL 08829/0155-0064	03/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO INTRODUCE A NEW RISK MANAGEMENT PLAN. CONSEQUENTLY, THE

								RD) - CMS		RMP DOCUMENT M.1.8.2 HAS BEEN UPDATED.
PL 04569/0925	AZITHROMYCIN 250MG FILM COATED TABLETS	GRANTED	PL 04569/0925-0033	PL 04569/0925-0033	03/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.6, AND 10 FOR THE GENERIC MEDICINAL PRODUCT FOLLOWING ASSESSMENT OF THE SAME CHANGE FOR THE REFERENCE PRODUCT ZITHROMAX (PFIZER).
PL 04569/0926	AZITHROMYCIN 500MG FILM COATED TABLETS	GRANTED	PL 04569/0926-0031	PL 04569/0926-0031	03/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.6, AND 10 FOR THE GENERIC MEDICINAL PRODUCT FOLLOWING ASSESSMENT OF THE SAME CHANGE FOR THE REFERENCE PRODUCT ZITHROMAX (PFIZER).
PL 17780/0944	OPIODUR 12 MICROGRAMS/HOUR TRANSDERMAL PATCH	GRANTED	PL 17780/0944-0002	PL 17780/0944-0002	09/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO SUBMIT A NEW RISK MANAGEMENT PLAN, (RMP).
PL 17780/0945	OPIODUR 25 MICROGRAMS/HOUR TRANSDERMAL PATCH	GRANTED	PL 17780/0945-0002	PL 17780/0945-0002	09/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO SUBMIT A NEW RISK MANAGEMENT PLAN, (RMP).
PL 17780/0946	OPIODUR 50 MICROGRAMS/HOUR TRANSDERMAL PATCH	GRANTED	PL 17780/0	PL 17780/0	09/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO SUBMIT A NEW RISK MANAGEMENT PLAN, (RMP).

			946-0002	946-0002				(STANDARD) - CMS		
PL 17780/0947	OPIODUR 75 MICROGRAMS/HOUR TRANSDERMAL PATCH	GRANTED	PL 17780/0947-0002	PL 17780/0947-0002	09/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO SUBMIT A NEW RISK MANAGEMENT PLAN, (RMP).
PL 17780/0948	OPIODUR 100 MICROGRAMS/HOUR TRANSDERMAL PATCH	GRANTED	PL 17780/0948-0002	PL 17780/0948-0002	09/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO SUBMIT A NEW RISK MANAGEMENT PLAN, (RMP).
PL 04416/1600	EBETREX 10MG/ML SOLUTION FOR INJECTION, PRE-FILLED SYRINGE	GRANTED	PL 04416/1600-0005	PL 04416/1600-0005	13/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 AND 5.1 OF THE SMPC AND PIL 1)TO THE PRODUCT INFORMATION OF SMPC FOR LANTAREL FS® 7,5 MG/10 MG/15 MG/20 MG/25 MG INJEKTIONSLÖSUNG (METHOTREXATE), PFIZER PHARMA PFE GMBH, GERMANY, DATED MARCH 2018 AND 2) RELEVANT PUBLICATIONS CONTAINING IMPORTANT NEW SAFETY AND EFFICACY INFORMATION AND ON THE OFFICIAL REGULATORY HEALTH AUTHORITY

										INFORMATION PUBLISHED ON WEBSITES.
PL 04416/1600	EBETREX 10MG/ML SOLUTION FOR INJECTION, PRE-FILLED SYRINGE	GRANTED	PL 04416/1600-0005	PL 04416/1600-0005	13/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 AND 5.1 OF THE SMPC AND PIL 1)TO THE PRODUCT INFORMATION OF SMPC FOR LANTAREL FS® 7,5 MG/10 MG/15 MG/20 MG/25 MG INJEKTIONSLÖSUNG (METHOTREXATE), PFIZER PHARMA PFE GMBH, GERMANY, DATED MARCH 2018 AND 2) RELEVANT PUBLICATIONS CONTAINING IMPORTANT NEW SAFETY AND EFFICACY INFORMATION AND ON THE OFFICIAL REGULATORY HEALTH AUTHORITY INFORMATION PUBLISHED ON WEBSITES.
PL 05003/0041	ESMERON 10MG/ML SOLUTION FOR INJECTION	GRANTED	PL 05003/0041-0096	PL 05003/0041-0096	16/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-2, 4-4 AND LABEL IN LINE WITH UPDATES TO THE CCDS, WARNINGS APPLYING TO HEALTHCARE PROFESSIONALS TO HELP PREVENT

										ACCIDENTAL ADMINISTRATION.
PL 46602/0004	RABIES VACCINE BP > 2.5 IU/ML, POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 46602/0004-0025	PL 46602/0004-0025	18/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1. 4.2, 4.4, 4.5, 4.6, 4.8, 5.1 AND 6.6 OF THE SMPC AND PIL OF SANOFI PASTEUR (SP) RABIES HDCV (HUMAN DIPLOID CELL VACCINE) WITH SUPPORTIVE DATA ISSUED FROM ADULT AND PEDIATRIC CLINICAL STUDIES.
PL 00010/0526	DIANETTE TABLETS	GRANTED	PL 00010/0526-0060	PL 00010/0526-0060	18/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO SUBMIT THE STUDY REPORT OF THE EXTENSION STUDY/FOLLOW-UP STUDY WHICH WAS REQUESTED IN THE FINAL ASSESSMENT REPORT EMA/101714/2017 (DATED 1 DECEMBER 2016), AT THE END OF THE PASS PROGRAMME.
PL 17901/0263	VIMOVO 500 MG/20 MG MODIFIED-RELEASE TABLETS	GRANTED	PL 17901/0263-0042	PL 17901/0263-0042	22/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.5 AND 4.8 OF THE SMPC FOR VIMOVO FOLLOWING AN UPDATE TO THE CORE DATA SHEET (CDS) ADDITIONALLY THE SECTION 2 OF PIL

										HAS BEEN UPDATED IN LINE WITH QRD TEMPLATE AND THE ADVERSE REPORTING SECTION OF THE SMPC AND PIL HAVE BEEN UPDATED IN LINE WITH APPENDIX V.
PL 10085/0039	GRAZAX 75,000 SQ-T ORAL LYOPHILISATE	GRANTED	PL 10085/0039-0058	PL 10085/0039-0058	25/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND PIL AFTER RE-ASSESSING ADRS USING A REFINED METHODOLOGY. IN ADDITION, DATA FROM ONE CLINICAL TRIAL ARE INCLUDED IN THE APPLICATION.
PL 03551/0133	AMINOPLASMAL PAEDIATRIC 10% SOLUTION FOR INFUSION	GRANTED	PL 03551/0133-0026	PL 03551/0133-0026	26/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE THE SPC (SECTIONS 1, 2, 3, 4.1, 4.2, 4.3, 4.4, 4.8, 4.9, 5.1, 5.2, 5.3, 6.2, 6.3, 6.4, 6.5, 6.6), LABELS, & PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA AND QRD TEMPLATE. ADDITIONALLY SEVERAL SENTENCES HAVE BEEN AMENDED IN THE SPC TEXT FOR EASIER COMPREHENSION WITHOUT ANY NEW

										DATA/INFORMATION/LITERATURE OR CHANGE IN CONTENT¿ ACCORDING TO COMMISSION REGULATION (EC)¿ (1234/2008 CMDH/132/2009/REV 45). **NB: SPC 6.5, 6.6; LABELS & PIL INDEXED TO INPUT FOLDER, MARKED AS 'FINAL AGREED', AS THESE HAVE BEEN UPDATED SUBSEQUENTLY VIA SUBMISSION 0029**
PL 03551/0133	AMINOPLASMAL PAEDIATRIC 10% SOLUTION FOR INFUSION	GRANTED	PL 03551/0133-0026	PL 03551/0133-0026	26/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE THE SPC (SECTIONS 1, 2, 3, 4.1, 4.2, 4.3, 4.4, 4.8, 4.9, 5.1, 5.2, 5.3, 6.2, 6.3, 6.4, 6.5, 6.6), LABELS, & PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA AND QRD TEMPLATE. ADDITIONALLY SEVERAL SENTENCES HAVE BEEN AMENDED IN THE SPC TEXT FOR EASIER COMPREHENSION WITHOUT ANY NEW DATA/INFORMATION/LITERATURE OR

										CHANGE IN CONTENT¿ ACCORDING TO COMMISSION REGULATION (EC)¿ (1234/2008 CMDH/132/2009/REV 45). **NB: SPC 6.5, 6.6; LABELS & PIL INDEXED TO INPUT FOLDER, MARKED AS 'FINAL AGREED', AS THESE HAVE BEEN UPDATED SUBSEQUENTLY VIA SUBMISSION 0029**
PL 04416/1601	DOCETAXEL 10 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 04416/1601-0005	PL 04416/1601-0005	29/06/2020	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, 5.1, 6.3 & 6.6 OF THE SPC IN ORDER TO COMPLY WITH CURRENT COMPANY CORE DATA SHEET (CCDS). AS A CONSEQUENCE THE PIL HAS BEEN UPDATED.
PL 04569/0886	MOMETASONE FUROATE 0.1% W/W OINTMENT	GRANTED	PL 04569/0886-0033	PL 04569/0886-0033	29/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.2, 4.3, 4.4,4.8,5.1 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT LOCON 0.1% SALVA. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 02855/0276	NICABATE 14 MG/24 HRS TRANSDERMAL PATCHES	GRANTED	PL 02855/0276-0017	PL 02855/0276-0017	30/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO UPDATE TEXT RELATING TO PAEDIATRIC POPULATION AND CORRESPONDING PIL FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SMPC FRAGMENT 4.2 HAS BEEN UPDATED. 2. TO UPDATE TEXT RELATING TO WARNINGS AND PRECAUTIONS AND CORRESPONDING PIL FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SMPC FRAGMENT 4.4 HAS BEEN UPDATED. 3. TO UPDATE TEXT RELATING TO PREGNANCY, FERTILITY AND LACTATION AND CORRESPONDING PIL FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SMPC FRAGMENT 4.6

										HAS BEEN UPDATED. 4. TO UPDATE TEXT RELATING TO PRECLINICAL SAFETY DATA TO ALIGN WITH INFORMATION IN SECTION 4.6 REGARDING FERTILITY. CONSEQUENTLY, SMPC FRAGMENT 5.3 HAS BEEN UPDATED. 5. TO UPDATE TEXT RELATING TO SPECIAL PRECAUTIONS FOR DISPOSAL TO ALIGN WITH WARNING REGARDING DISPOSAL OF PATCHES IN SECTION 4.4. CONSEQUENTLY, SMPC FRAGMENT 6.6 HAS BEEN UPDATED. 6. TO UPDATE TEXT ENABLING NIQUITIN PATCHES TO BE USED IN COMBINATION WITH NIQUITIN ORAL FORMS IN SMPC, CORRESPONDING

										LEAFLET AND LABELLING. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 02855/0281	NICABATE 21 MG/24 HRS TRANSDERMAL PATCHES	GRANTED	PL 02855/0281-0018	PL 02855/0281-0018	30/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO UPDATE TEXT RELATING TO PAEDIATRIC POPULATION AND CORRESPONDING PIL FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SMPC FRAGMENT 4.2 HAS BEEN UPDATED. 2. TO UPDATE TEXT RELATING TO WARNINGS AND PRECAUTIONS AND CORRESPONDING PIL FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SMPC FRAGMENT 4.4 HAS BEEN UPDATED. 3. TO UPDATE TEXT RELATING TO PREGNANCY, FERTILITY AND LACTATION AND CORRESPONDING PIL

										FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SMPC FRAGMENT 4.6 HAS BEEN UPDATED. 4. TO UPDATE TEXT RELATING TO PRECLINICAL SAFETY DATA TO ALIGN WITH INFORMATION IN SECTION 4.6 REGARDING FERTILITY. CONSEQUENTLY, SMPC FRAGMENT 5.3 HAS BEEN UPDATED. 5. TO UPDATE TEXT RELATING TO SPECIAL PRECAUTIONS FOR DISPOSAL TO ALIGN WITH WARNING REGARDING DISPOSAL OF PATCHES IN SECTION 4.4. CONSEQUENTLY, SMPC FRAGMENT 6.6 HAS BEEN UPDATED. 6. TO UPDATE TEXT ENABLING NIQUITIN

										PATCHES TO BE USED IN COMBINATION WITH NIQUITIN ORAL FORMS IN SMPC, CORRESPONDING LEAFLET AND LABELLING. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 02855/0282	NICABATE 7 MG/24 HRS TRANSDERMAL PATCHES	GRANTED	PL 02855/0282-0017	PL 02855/0282-0017	30/06/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO UPDATE TEXT RELATING TO PAEDIATRIC POPULATION AND CORRESPONDING PIL FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SMPC FRAGMENT 4.2 HAS BEEN UPDATED. 2. TO UPDATE TEXT RELATING TO WARNINGS AND PRECAUTIONS AND CORRESPONDING PIL FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SMPC FRAGMENT 4.4 HAS BEEN UPDATED. 3. TO UPDATE TEXT

										RELATING TO PREGNANCY, FERTILITY AND LACTATION AND CORRESPONDING PIL FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SMPC FRAGMENT 4.6 HAS BEEN UPDATED. 4. TO UPDATE TEXT RELATING TO PRECLINICAL SAFETY DATA TO ALIGN WITH INFORMATION IN SECTION 4.6 REGARDING FERTILITY. CONSEQUENTLY, SMPC FRAGMENT 5.3 HAS BEEN UPDATED. 5. TO UPDATE TEXT RELATING TO SPECIAL PRECAUTIONS FOR DISPOSAL TO ALIGN WITH WARNING REGARDING DISPOSAL OF PATCHES IN SECTION 4.4. CONSEQUENTLY, SMPC FRAGMENT 6.6 HAS BEEN UPDATED.

										6. TO UPDATE TEXT ENABLING NIQUITIN PATCHES TO BE USED IN COMBINATION WITH NIQUITIN ORAL FORMS IN SMPC, CORRESPONDING LEAFLET AND LABELLING. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04416/0784	BUDESONIDE 64 MICROGRAMS/ACTUATION, AQUEOUS NASAL SPRAY	GRANTED	PL 04416/0784-0039	PL 04416/0784-0039	01/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	.TO UPDATE SECTION 4.2, 4.4, 4.5, 4.6, 4.8,4.9, 5.1, 5.2 OF THE SPC OF BULDESONIDE 64 MICROGRAMS/ACTUATION IN LINE WITH THE REFERENCE MEDICINAL PRODUCT I.E., PULMICORT TOPINASAL NASENSPRAY. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED
PL 41042/0001	DUODOPA 20MG/ML + 5MG/ML, INTESTINAL GEL	GRANTED	PL 41042/0001-0046	PL 41042/0001-0046	01/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATED RISK MANAGEMENT PLAN FOR LEVODOPA/CARBIDOPA INTESTINAL GEL IN ACCORDANCE WITH GVP MODULE V REVISION 2.

PL 04416/1091	RISEDRONATE SODIUM AND CALCIUM / CHOLECALCIFEROL 35 MG + 1000 MG / 880 IU TABLETS	GRANTED	PL 04416/1091-0045	PL 04416/1091-0045	02/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 02, 03, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1, 5.2, 6.1, 6.5 AND 6.6 OF THE SMPC AND PIL TO BIBLIOGRAPHIC DATA DUE TO THE REASON THAT REGULATORY REFERENCE PRODUCT ACTONEL COMBI WAS WITHDRAWN FROM THE MARKET.
PL 50622/0044	LUSTRAL 100MG FILM COATED TABLETS	GRANTED	PL 50622/0044-0016	PL 50622/0044-0016	02/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO PROVIDE AN UPDATE ON THE STATUS OF STUDY A0501093 ¿SPRITES: SERTRALINE PEDIATRIC REGISTRY FOR THE EVALUATION OF SAFETY - A NON-INTERVENTIONAL, LONGITUDINAL, COHORT STUDY TO EVALUATE THE EFFECTS OF LONG-TERM SERTRALINE TREATMENT IN CHILDREN AND ADOLESCENTS. IN ADDITION, THIS SUBMISSION INCLUDES THE MAH¿S RESPONSE TO COMMENT¿S IN THE RMS¿S FINAL VARIATION ASSESSMENT REPORT

										(FVAR) FOLLOWING CONCLUSION OF VARIATION PROCEDURE NL/H/XXXX/WS/309.
PL 50622/0045	LUSTRAL 50MG FILM COATED TABLETS	GRANTED	PL 50622/0045-0016	PL 50622/0045-0016	02/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO PROVIDE AN UPDATE ON THE STATUS OF STUDY A0501093 ¿SPRITES: SERTRALINE PEDIATRIC REGISTRY FOR THE EVALUATION OF SAFETY - A NON-INTERVENTIONAL, LONGITUDINAL, COHORT STUDY TO EVALUATE THE EFFECTS OF LONG-TERM SERTRALINE TREATMENT IN CHILDREN AND ADOLESCENTS. IN ADDITION, THIS SUBMISSION INCLUDES THE MAH¿S RESPONSE TO COMMENT¿S IN THE RMS¿S FINAL VARIATION ASSESSMENT REPORT (FVAR) FOLLOWING CONCLUSION OF VARIATION PROCEDURE NL/H/XXXX/WS/309.
PL 50622/0056	SERTRALINE 100MG FILM-COATED TABLETS	GRANTED	PL 50622/0056-0010	PL 50622/0056-0010	02/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO PROVIDE AN UPDATE ON THE STATUS OF STUDY A0501093 ¿SPRITES:

								RD) - CMS WORKSHARING		SERTRALINE PEDIATRIC REGISTRY FOR THE EVALUATION OF SAFETY - A NON-INTERVENTIONAL, LONGITUDINAL, COHORT STUDY TO EVALUATE THE EFFECTS OF LONG-TERM SERTRALINE TREATMENT IN CHILDREN AND ADOLESCENTS. IN ADDITION, THIS SUBMISSION INCLUDES THE MAH¿S RESPONSE TO COMMENT¿S IN THE RMS¿S FINAL VARIATION ASSESSMENT REPORT (FVAR) FOLLOWING CONCLUSION OF VARIATION PROCEDURE NL/H/XXXX/WS/309.
PL 50622/0057	SERTRALINE 50MG FILM-COATED TABLETS	GRANTED	PL 50622/0057-0010	PL 50622/0057-0010	02/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO PROVIDE AN UPDATE ON THE STATUS OF STUDY A0501093 ¿SPRITES: SERTRALINE PEDIATRIC REGISTRY FOR THE EVALUATION OF SAFETY - A NON-INTERVENTIONAL, LONGITUDINAL, COHORT STUDY TO EVALUATE THE EFFECTS OF LONG-

										TERM SERTRALINE TREATMENT IN CHILDREN AND ADOLESCENTS. IN ADDITION, THIS SUBMISSION INCLUDES THE MAH¿S RESPONSE TO COMMENT¿S IN THE RMS¿S FINAL VARIATION ASSESSMENT REPORT (FVAR) FOLLOWING CONCLUSION OF VARIATION PROCEDURE NL/H/XXXX/WS/309.
PL 04416/1296	COPRALINEB 0.5 MG/2.5 MG PER 2.5 ML NEBULISER SOLUTION	GRANTED	PL 04416/1296-0026	PL 04416/1296-0026	03/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8 AND 4.9 OF THE SMPC AND THE PIL TO THE NOT HARMONISED REFERENCE PRODUCT COMBIVENT UNIT DOSE, BOEHRINGER INGELHEIM B.V., JANUARY 2018.
PL 00025/0637	VARICELLA VACCINE (LIVE)	GRANTED	PL 00025/0637-0056	PL 00025/0637-0056	07/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	[1] TO REGISTER AN UPDATED RMP (FROM RMP VERSION 1.0, DATED 19-NOV-2018 TO RMP VERSION 1.1) TO FURTHER CHARACTERISE THE RISK OF SECONDARY TRANSMISSION.

										[2] TO UPDATE SECTIONS 1, 2, 4.3, 4.4, 6.2, 6.3, 6.4, 6.5 AND 6.6 OF THE SMPC TO FURTHER CHARACTERISE THE RISK OF SECONDARY TRANSMISSION. ADDITIONALLY, UPDATES HAVE BEEN MADE IN LINE WITH THE EXCIPIENT'S GUIDELINE AND QRD TEMPLATE V10.1. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00025/0637	VARICELLA VACCINE (LIVE)	GRANTED	PL 00025/0637-0056	PL 00025/0637-0056	07/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	[1] TO REGISTER AN UPDATED RMP (FROM RMP VERSION 1.0, DATED 19-NOV-2018 TO RMP VERSION 1.1) TO FURTHER CHARACTERISE THE RISK OF SECONDARY TRANSMISSION. [2] TO UPDATE SECTIONS 1, 2, 4.3, 4.4, 6.2, 6.3, 6.4, 6.5 AND 6.6 OF THE SMPC TO FURTHER CHARACTERISE THE RISK OF SECONDARY TRANSMISSION. ADDITIONALLY,

										UPDATES HAVE BEEN MADE IN LINE WITH THE EXCIPIENT'S GUIDELINE AND QRD TEMPLATE V10.1. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00025/0637	VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 00025/0637-0056	PL 00025/0637-0056	07/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	[1] TO REGISTER AN UPDATED RMP (FROM RMP VERSION 1.0, DATED 19-NOV-2018 TO RMP VERSION 1.1) TO FURTHER CHARACTERISE THE RISK OF SECONDARY TRANSMISSION. [2] TO UPDATE SECTIONS 1, 2, 4.3, 4.4, 6.2, 6.3, 6.4, 6.5 AND 6.6 OF THE SMPC TO FURTHER CHARACTERISE THE RISK OF SECONDARY TRANSMISSION. ADDITIONALLY, UPDATES HAVE BEEN MADE IN LINE WITH THE EXCIPIENT'S GUIDELINE AND QRD TEMPLATE V10.1. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 00025/0637	VARIVAX POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 00025/0637-0056	PL 00025/0637-0056	07/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	[1] TO REGISTER AN UPDATED RMP (FROM RMP VERSION 1.0, DATED 19-NOV-2018 TO RMP VERSION 1.1) TO FURTHER CHARACTERISE THE RISK OF SECONDARY TRANSMISSION. [2] TO UPDATE SECTIONS 1, 2, 4.3, 4.4, 6.2, 6.3, 6.4, 6.5 AND 6.6 OF THE SMPC TO FURTHER CHARACTERISE THE RISK OF SECONDARY TRANSMISSION. ADDITIONALLY, UPDATES HAVE BEEN MADE IN LINE WITH THE EXCIPIENT'S GUIDELINE AND QRD TEMPLATE V10.1. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0666	MAINTELYTE SOLUTION FOR INFUSION	GRANTED	PL 00116/0666-0002	PL 00116/0666-0002	09/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.9, 5.2 AND 6.2 OF THE SPC TO INTRODUCE THE POST APPROVAL CHANGES COMMITTED DURING THE REPEAT USE PROCEDURE (SE/H/921/001/E01). CONSEQUENTLY,

										IMPACTING THE PIL AND LABEL. IN ADDITION THE PACKAGE LEAFLET, OUTER AND IMMEDIATE LABELLING HAVE BEEN UPDATED IN LINE WITH THE MOST RECENT QRD TEMPLATE.
PL 02855/0277	NICABATE CLEAR 14 MG/24 HRS TRANSDERMAL PATCH	GRANTED	PL 02855/0277-0020	PL 02855/0277-0020	09/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.6, 5.3 AND 6.6 OF THE SMPC IN LINE WITH THE COMPANY CORE SAFETY INFORMATION (CCSI). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 02855/0279	NICABATE CLEAR 21 MG/24 HRS TRANSDERMAL PATCH	GRANTED	PL 02855/0279-0019	PL 02855/0279-0019	09/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.6, 5.3 AND 6.6 OF THE SMPC IN LINE WITH THE COMPANY CORE SAFETY INFORMATION (CCSI). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE

										CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 02855/0283	NICABATE CLEAR 7 MG/24 HRS TRANSDERMAL PATCH	GRANTED	PL 02855/0283-0019	PL 02855/0283-0019	09/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.6, 5.3 AND 6.6 OF THE SMPC IN LINE WITH THE COMPANY CORE SAFETY INFORMATION (CCSI). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00057/0987	GENOTROPIN 5.3 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0987-0047	PL 00057/0987-0047	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM

										POST MARKETING EXPERIENCE.
PL 00057/0988	GENOTROPIN 12MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0988-0045	PL 00057/0988-0045	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM POST MARKETING EXPERIENCE.
PL 00057/0989	GENOTROPIN MINIQUICK 0.2MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0989-0044	PL 00057/0989-0044	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM POST MARKETING EXPERIENCE.

PL 00057/0990	GENOTROPIN MINIQUICK 0.4MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0990-0043	PL 00057/0990-0043	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM POST MARKETING EXPERIENCE.
PL 00057/0991	GENOTROPIN MINIQUICK 0.6MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0991-0043	PL 00057/0991-0043	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM POST MARKETING EXPERIENCE.
PL 00057/0992	GENOTROPIN MINIQUICK 0.8MG POWDER AND SOLVENT FOR	GRANTED	PL 00057/0992-0042	PL 00057/0992-0042	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS

	SOLUTION FOR INJECTION							RD) - CMS		CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM POST MARKETING EXPERIENCE.
PL 00057/0993	GENOTROPIN MINIQUICK 1.0MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0993-0043	PL 00057/0993-0043	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM POST MARKETING EXPERIENCE.
PL 00057/0994	GENOTROPIN MINIQUICK 1.2MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0994-0043	PL 00057/0994-0043	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF

										INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM POST MARKETING EXPERIENCE.
PL 00057/0995	GENOTROPIN MINIQUICK 1.4MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0995-0043	PL 00057/0995-0043	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM POST MARKETING EXPERIENCE.
PL 00057/0996	GENOTROPIN MINIQUICK 1.6MG POWDER AND SOVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0996-0044	PL 00057/0996-0044	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM

										POST MARKETING EXPERIENCE.
PL 00057/0997	GENOTROPIN MINIQUICK 1.8MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0997-0043	PL 00057/0997-0043	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM POST MARKETING EXPERIENCE.
PL 00057/0998	GENOTROPIN MINIQUICK 2.0MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	GRANTED	PL 00057/0998-0043	PL 00057/0998-0043	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.6 AND 4.8 OF THE SPC FOR THE GENOTROPIN PRODUCTS CONCERNED IMPLEMENTING CHANGES TO THIS SECTION RELATED TO INCLUSION OF INFORMATION ON NON-SERIOUS HYPERSENSITIVITY REACTIONS THAT HAS COME TO LIGHT FROM POST MARKETING EXPERIENCE.

PL 04500/0005	INTRATECT 50 G/L SOLUTION FOR INFUSION	GRANTED	PL 04500/0005-0080	PL 04500/0005-0080	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SPC TO COMPRISE THE UPDATE OF THE 'SLOWINFUSION RATE'. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 04500/0013	INTRATECT 100 G/L, SOLUTION FOR INFUSION	GRANTED	PL 04500/0013-0058	PL 04500/0013-0058	10/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SPC TO COMPRISE THE UPDATE OF THE 'SLOWINFUSION RATE'. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 31750/0043	BUPRENORPHINE 2 MG SUBLINGUAL TABLETS	GRANTED	PL 31750/0043-0032	PL 31750/0043-0032	13/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.6, 4.7, 4.8 AND 4.9 OF THE SMPC IN LINE WITH THE NOT HARMONISED REFERENCE PRODUCT, SUBUTEX (MAH: INDIVIOR UK LIMITED - PL 36699/0002). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 31750/0044	BUPRENORPHINE 8 MG SUBLINGUAL TABLETS	GRANTED	PL 31750/0044-0033	PL 31750/0044-0033	13/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.6, 4.7, 4.8 AND 4.9 OF THE SMPC IN LINE WITH THE NOT HARMONISED REFERENCE PRODUCT, SUBUTEX (MAH: INDIVIOR UK

										LIMITED - PL 36699/0002). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00015/0325	ACTILYSE CATHFLO 2 MG POWDER FOR SOLUTION FOR INJECTION AND INFUSION	GRANTED	PL 00015/0325-0073	PL 00015/0325-0073	13/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FROM VERSION 3.3 TO VERSION 4.0 FOR ACTILYSE CATHFLO 2 MG POWDER FOR SOLUTION FOR INJECTION AND INFUSION.
PL 04416/0460	ENALAPRIL MALEATE/HYDROCHLOROTHIAZIDE 20/12.5MG TABLETS	GRANTED	PL 04416/0460-0034	PL 04416/0460-0034	16/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4 AND 4.5 OF THE SPC WITH INSERTION OF A WARNING FOR ACUTE MYOPIA AND SECONDARY ANGLE-CLOSURE GLAUCOMA, AND INSERTION OF A WARNING FOR DUAL BLOCKADE OF THE RENIN-ANGIOTENSIN SYSTEM. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 04416/1251	AMISULPRIDE 50MG TABLETS	GRANTED	PL 04416/1251-0029	PL 04416/1251-0029	16/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.2, 5.3, 6.1, 6.5 AND 6.6 OF THE SMPC AND PIL TO ADOPT TO NOT HARMONISED REFERENCE

										PRODUCT SOLIAN BY SANOFI-AVENTIS.
PL 04416/1252	AMISULPRIDE 100MG TABLETS	GRANTED	PL 04416/1252-0029	PL 04416/1252-0029	16/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.2, 5.3, 6.1, 6.5 AND 6.6 OF THE SMPC AND PIL TO ADOPT TO NOT HARMONISED REFERENCE PRODUCT SOLIAN BY SANOFI-AVENTIS.
PL 04416/1253	AMISULPRIDE 200MG TABLETS	GRANTED	PL 04416/1253-0030	PL 04416/1253-0030	16/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.2, 5.3, 6.1, 6.5 AND 6.6 OF THE SMPC AND PIL TO ADOPT TO NOT HARMONISED REFERENCE PRODUCT SOLIAN BY SANOFI-AVENTIS.
PL 04416/1254	AMISULPRIDE 400MG FILM-COATED TABLETS	GRANTED	PL 04416/1254-0027	PL 04416/1254-0027	16/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.2, 5.3, 6.1, 6.5 AND 6.6 OF THE SMPC AND PIL TO ADOPT TO NOT HARMONISED REFERENCE PRODUCT SOLIAN BY SANOFI-AVENTIS.
PL 10592/0302	FLUARIX TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 10592/0302-0083	PL 10592/0302-0083	17/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATED RMP (FROM V11 TO V12), MODIFIED ACCORDING TO THE GUIDELINE ON GOOD PHARMACOVIGILANCE

										PRACTICES (GVP) MODULE V - RISK MANAGEMENT SYSTEMS (REV 2) DATED 28 MARCH 2017: EMA/838713/2011 REV 2.
PL 10592/0302	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	GRANTED	PL 10592/0302-0083	PL 10592/0302-0083	17/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATED RMP (FROM V11 TO V12), MODIFIED ACCORDING TO THE GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP) MODULE V - RISK MANAGEMENT SYSTEMS (REV 2) DATED 28 MARCH 2017: EMA/838713/2011 REV 2.
PL 04569/1132	PERINDOPRIL ARGININE 2.5 MG FILM-COATED TABLETS	GRANTED	PL 04569/1132-0017	PL 04569/1132-0017	23/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5 AND PIL IN LINE WITH AN INTERNAL SAFETY SIGNAL CONCERNING THE DRUG INTERACTION OF GENERIC ACE INHIBITORS AND NEPRILYS INHIBITORS, WHICH RESULTS IN AN INCREASED RISK OF ANGIOEDEMA. QRD UPDATES ARE ALSO MADE.
PL 04569/1133	PERINDOPRIL ARGININE 5 MG FILM-COATED TABLETS	GRANTED	PL 04569/1133-0017	PL 04569/1133-0017	23/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5 AND PIL IN LINE WITH AN INTERNAL SAFETY

								RD) - CMS		SIGNAL CONCERNING THE DRUG INTERACTION OF GENERIC ACE INHIBITORS AND NEPRILYS INHIBITORS, WHICH RESULTS IN AN INCREASED RISK OF ANGIOEDEMA. QRD UPDATES ARE ALSO MADE.
PL 04569/1134	PERINDOPRIL ARGININE 10 MG FILM-COATED TABLETS	GRANTED	PL 04569/1134-0017	PL 04569/1134-0017	23/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 4-3, 4-4, 4-5 AND PIL IN LINE WITH AN INTERNAL SAFETY SIGNAL CONCERNING THE DRUG INTERACTION OF GENERIC ACE INHIBITORS AND NEPRILYS INHIBITORS, WHICH RESULTS IN AN INCREASED RISK OF ANGIOEDEMA. QRD UPDATES ARE ALSO MADE.
PL 00063/0579	NUROMOL 200MG/500MG TABLETS	GRANTED	PL 00063/0579-0044	PL 00063/0579-0044	27/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.4, 4.6, 4.8.4.9 AND 5.1 OF THE SMPC AND PIL IN LINE WITH COMPANY CORE DATE SHEET (CCDS) AND TO UPDATE THE PIL AND LABELLING IN LINE WITH THE EXCIPIENT OF MEDICAL PRODUCT FOR HUMAN USE GUIDELINE.

PL 06958/0031	AZZALURE, 10 SPEYWOOD UNITS/0.05ML, POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 06958/0031-0067	PL 06958/0031-0067	27/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO CHANGE THE FREQUENCY CATEGORY FOR EYE MOVEMENT DISORDER FROM ¿UNCOMMON¿ TO ¿RARE¿ FOR THE INDICATION OF MODERATE TO SEVERE GLABELLAR LINES IN SMPC 4-8. CONSEQUENTLY, THE PIL IS UPDATED, SECTION 2-0 IS ALSO UPDATED WITH AN EDITORIAL CHANGE.
PL 34926/0009	BOTULINUM TOXIN TYPE A 500 UNITS POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 34926/0009-0077	PL 34926/0009-0077	27/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO CHANGE THE FREQUENCY CATEGORY FOR EYE MOVEMENT DISORDER FROM ¿UNCOMMON¿ TO ¿RARE¿ FOR THE INDICATION OF MODERATE TO SEVERE GLABELLAR LINES IN SMPC 4-8. CONSEQUENTLY, THE PIL IS UPDATED, SECTION 2-0 IS ALSO UPDATED WITH AN EDITORIAL CHANGE.
PL 34926/0015	BOTULINUM TOXIN TYPE A 300 UNITS POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 34926/0015-0068	PL 34926/0015-0068	27/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO CHANGE THE FREQUENCY CATEGORY FOR EYE MOVEMENT DISORDER FROM ¿UNCOMMON¿ TO ¿RARE¿ FOR THE

								WORKSHARING		INDICATION OF MODERATE TO SEVERE GLABELLAR LINES IN SMPC 4-8. CONSEQUENTLY, THE PIL IS UPDATED, SECTION 2-0 IS ALSO UPDATED WITH AN EDITORIAL CHANGE.
PL 04569/1227	EPROSARTAN MYLAN 300 MG FILM-COATED TABLETS	GRANTED	PL 04569/1227-0028	PL 04569/1227-0028	29/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS AND PRECAUTIONS FOR USE) AND 4.5 (INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION) OF THE SPC AND CONSEQUENTIALLY THE LEAFLET IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS).
PL 04569/1228	EPROSARTAN MYLAN 400 MG FILM-COATED TABLETS	GRANTED	PL 04569/1228-0031	PL 04569/1228-0031	29/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS AND PRECAUTIONS FOR USE) AND 4.5 (INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION) OF THE SPC AND CONSEQUENTIALLY THE LEAFLET IN LINE WITH THE COMPANY

										CORE DATA SHEET (CCDS).
PL 04569/1229	EPROSARTAN MYLAN 600 MG FILM-COATED TABLETS	GRANTED	PL 04569/1229-0028	PL 04569/1229-0028	29/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 (SPECIAL WARNINGS AND PRECAUTIONS FOR USE) AND 4.5 (INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION) OF THE SPC AND CONSEQUENTIALLY THE LEAFLET IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS).
PL 00010/0571	YASMIN 0.03 MG/3 MG FILM-COATED TABLETS	GRANTED	PL 00010/0571-0060	PL 00010/0571-0060	29/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.2, 4.4 AND 4.8 OF THE SMPC IN LINE WITH THE QRD TEMPLATE OF THE EUROPEAN MEDICINES AGENCY'S (EMA) WORKING GROUP ON QUALITY REVIEW OF DOCUMENTS.
PL 44124/0015	DEXAMETHASONE 3.3 MG/ML, SOLUTION FOR INJECTION	GRANTED	PL 44124/0015-0004	PL 44124/0015-0004	31/07/2020	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 SIGNAL ASSESSMENT REPORT. CONSEQUENTLY, IMPACTING THE PIL.

PL 34926/0002	DECAPEPTYL SR 3MG, POWDER FOR SUSPENSION FOR INJECTION	GRANTED	PL 34926/0002-0055	PL 34926/0002-0055	31/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE RMP
PL 34926/0003	DECAPEPTYL SR 11.25 MG, POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 34926/0003-0043	PL 34926/0003-0043	31/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE RMP
PL 34926/0012	SALVACYL 11.25MG POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 34926/0012-0079	PL 34926/0012-0079	31/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE RMP
PL 34926/0013	DECAPEPTYL SR 22.5MG POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION.	GRANTED	PL 34926/0013-0055	PL 34926/0013-0055	31/07/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE RMP
PL 04416/0484	AMOXICILLIN 125MG/5ML POWDER FOR ORAL SUSPENSION	GRANTED	PL 04416/0484-0060	PL 04416/0484-0060	02/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENT TO INCLUDE THE ADR ¿ASEPTIC MENINGITIS¿ BASED ON SCIENTIFIC

								WORKSHARING		LITERATURE DATA VIA WORK-SHARING PROCEDURE TO RECEIVE A HARMONISED OUTCOME. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04416/0485	AMOXICILLIN 250MG/5ML POWDER FOR ORAL SUSPENSION	GRANTED	PL 04416/0485-0059	PL 04416/0485-0059	02/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENT TO INCLUDE THE ADR ¿ASEPTIC MENINGITIS¿ BASED ON SCIENTIFIC LITERATURE DATA VIA WORK-SHARING PROCEDURE TO RECEIVE A HARMONISED OUTCOME. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04416/0576	AMOXICILLIN 250MG HARD CAPSULES	GRANTED	PL 04416/0576-0071	PL 04416/0576-0071	02/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENT TO INCLUDE THE ADR ¿ASEPTIC MENINGITIS¿ BASED ON SCIENTIFIC LITERATURE DATA VIA WORK-SHARING PROCEDURE TO RECEIVE A HARMONISED

										OUTCOME. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04416/0577	AMOXICILLIN 500MG HARD CAPSULES	GRANTED	PL 04416/0577-0073	PL 04416/0577-0073	02/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENT TO INCLUDE THE ADR ¿ASEPTIC MENINGITIS¿ BASED ON SCIENTIFIC LITERATURE DATA VIA WORK-SHARING PROCEDURE TO RECEIVE A HARMONISED OUTCOME. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 14338/0008	PARACETAMOL 500 MG, CAPSULES, SOFT	GRANTED	PL 14338/0008-0013	PL 14338/0008-0013	03/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1,2, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 6.1, 6.5 AND 7 OF THE SMPC, PIL AND LABELLING RAISED BY IE & NL AFTER APPROVAL OF THE RUP PROCEDURE (UK/H/5685/001/E/001).
PL 44673/0091	PANADOL COLD AND FLU	GRANTED	PL 44673/0091-0015	PL 44673/0091-0015	05/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	[1] TO UPDATE THE SPC (SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.2, 5.3) BASED ON THE UPDATED GSK CH RSI FOR FIXED-DOSE COMBINATION

								GROUPING		MEDICINAL PRODUCTS CONTAINING PARACETAMOL AND PSEUDOEPHEDRINE HYDROCHLORIDE AS ACTIVE SUBSTANCES. A WARNING OF ' ISCHAEMIC COLITIS' HAS BEEN ADDED TO SECTION 4.4 OF THE SMPC AS PER THE RECOMMENDATION FROM THE PRAC PSUR SINGLE ASSESSMENT REPORT DATED 14 FEBRUARY 2019 ON ACTIVE SUBSTANCES: PARACETAMOL / PSEUDOEPHEDRINE (PSUSA/00002307/201806). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE AND IN LINE WITH THE ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON ¿EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL

										PRODUCTS FOR HUMAN USE¿ (EMA/CHMP/302620/2017). CONSEQUENTIALLY, THE PIL & LABEL ARE UPDATED. [2] TO UPDATE THE RMP TO ALIGN WITH (GVP) MODULE V REVISION 2. **THE FINAL NATIONAL SPC (4.4 & 4.8) & PIL ALSO INCORPORATE THE PRAC RECOMMENDED CHANGES ON ISCHAEMIC OPTIC NEUROPATHY APPROVED ON 27/07/2020, AS PART OF SUBMISSION 0018 (IE/H/0835/001/1A/059)**
PL 44673/0091	PANADOL COLD AND FLU	GRANTED	PL 44673/0091-0015	PL 44673/0091-0015	05/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	[1] TO UPDATE THE SPC (SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.2, 5.3) BASED ON THE UPDATED GSK CHRSI FOR FIXED-DOSE COMBINATION MEDICINAL PRODUCTS CONTAINING PARACETAMOL AND PSEUDOEPHEDRINE HYDROCHLORIDE AS ACTIVE SUBSTANCES.

										A WARNING OF ' ISCHAEMIC COLITIS' HAS BEEN ADDED TO SECTION 4.4 OF THE SMPC AS PER THE RECOMMENDATION FROM THE PRAC PSUR SINGLE ASSESSMENT REPORT DATED 14 FEBRUARY 2019 ON ACTIVE SUBSTANCES: PARACETAMOL / PSEUDOEPHEDRINE (PSUSA/00002307/201806). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE AND IN LINE WITH THE ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON ¿EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE¿ (EMA/CHMP/302620/2017). CONSEQUENTIALLY, THE PIL & LABEL ARE UPDATED.

										[2] TO UPDATE THE RMP TO ALIGN WITH (GVP) MODULE V REVISION 2. **THE FINAL NATIONAL SPC (4.4 & 4.8) & PIL ALSO INCORPORATE THE PRAC RECOMMENDED CHANGES ON ISCHAEMIC OPTIC NEUROPATHY APPROVED ON 27/07/2020, AS PART OF SUBMISSION 0018 (IE/H/0835/001/1A/059)**
PL 39307/0070	AMISULPRIDE 100MG/ML SUGAR FREE ORAL SOLUTION	GRANTED	PL 39307/0070-0015	PL 39307/0070-0015	10/08/2020	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 AND 4.8 OF THE SMPC AND THE CORRESPONDING SECTIONS OF THE LEAFLET TO HARMONISE THE PRODUCT INFORMATION BETWEEN THE MEMBER STATES INVOLVED.
PL 00116/0641	TRIOMEL PERIPHERAL 4 G/L NITROGEN 700 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0641-0066	PL 00116/0641-0066	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

										IN ADDITION, THE PRODUCT CCDS HAS BEEN UPDATED TO INTRODUCE INFORMATION FOR INCOMPATIBILITY OF CONCOMITANT ADMINISTRATION WITH AMPICILLIN AND FOSPHENYTOIN. CONSEQUENTLY, THE PACKAGE LEAFLET HAS BEEN UPDATED. **PIL TEXT ONLY HAS BEEN SUPPLIED; THIS HAS BEEN RE-INDEXED TO THE INPUT FOLDER AS 'FINAL UK PIL TEXT'. PIL MOCK-UPS HAVE BEEN APPROVED SEPARATELY AS PART OF A 61(3) NOTIFICATION (COLLECTION ID 215154; GRANTED 23/08/2019).**
PL 00116/0641	TRIOMEL PERIPHERAL 4 G/L NITROGEN 700 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0641-0066	PL 00116/0641-0066	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

										IN ADDITION, THE PRODUCT CCDS HAS BEEN UPDATED TO INTRODUCE INFORMATION FOR INCOMPATIBILITY OF CONCOMITANT ADMINISTRATION WITH AMPICILLIN AND FOSPHENYTOIN. CONSEQUENTLY, THE PACKAGE LEAFLET HAS BEEN UPDATED. **PIL TEXT ONLY HAS BEEN SUPPLIED; THIS HAS BEEN RE-INDEXED TO THE INPUT FOLDER AS 'FINAL UK PIL TEXT'. PIL MOCK-UPS HAVE BEEN APPROVED SEPARATELY AS PART OF A 61(3) NOTIFICATION (COLLECTION ID 215154; GRANTED 23/08/2019).**
PL 00116/0641	TRIOMEL PERIPHERAL 4 G/L NITROGEN 700 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0641-0066	PL 00116/0641-0066	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

										IN ADDITION, THE PRODUCT CCDS HAS BEEN UPDATED TO INTRODUCE INFORMATION FOR INCOMPATIBILITY OF CONCOMITANT ADMINISTRATION WITH AMPICILLIN AND FOSPHENYTOIN. CONSEQUENTLY, THE PACKAGE LEAFLET HAS BEEN UPDATED. **PIL TEXT ONLY HAS BEEN SUPPLIED; THIS HAS BEEN RE-INDEXED TO THE INPUT FOLDER AS 'FINAL UK PIL TEXT'. PIL MOCK-UPS HAVE BEEN APPROVED SEPARATELY AS PART OF A 61(3) NOTIFICATION (COLLECTION ID 215154; GRANTED 23/08/2019).**
PL 00116/0642	TRIOMEL 5 G/L NITROGEN 990 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0642-0063	PL 00116/0642-0063	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

										IN ADDITION, THE PRODUCT CCDS HAS BEEN UPDATED TO INTRODUCE INFORMATION FOR INCOMPATIBILITY OF CONCOMITANT ADMINISTRATION WITH AMPICILLIN AND FOSPHENYTOIN. CONSEQUENTLY, THE PACKAGE LEAFLET HAS BEEN UPDATED. **PIL TEXT ONLY HAS BEEN SUPPLIED; THIS HAS BEEN RE-INDEXED TO THE INPUT FOLDER AS 'FINAL UK PIL TEXT'. PIL MOCK-UPS HAVE BEEN APPROVED SEPARATELY AS PART OF A 61(3) NOTIFICATION (COLLECTION ID 215154; GRANTED 23/08/2019).**
PL 00116/0642	TRIOMEL 5 G/L NITROGEN 990 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0642-0063	PL 00116/0642-0063	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

										IN ADDITION, THE PRODUCT CCDS HAS BEEN UPDATED TO INTRODUCE INFORMATION FOR INCOMPATIBILITY OF CONCOMITANT ADMINISTRATION WITH AMPICILLIN AND FOSPHENYTOIN. CONSEQUENTLY, THE PACKAGE LEAFLET HAS BEEN UPDATED. **PIL TEXT ONLY HAS BEEN SUPPLIED; THIS HAS BEEN RE-INDEXED TO THE INPUT FOLDER AS 'FINAL UK PIL TEXT'. PIL MOCK-UPS HAVE BEEN APPROVED SEPARATELY AS PART OF A 61(3) NOTIFICATION (COLLECTION ID 215154; GRANTED 23/08/2019).**
PL 00116/0642	TRIOMEL 5 G/L NITROGEN 990 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0642-0063	PL 00116/0642-0063	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

										IN ADDITION, THE PRODUCT CCDS HAS BEEN UPDATED TO INTRODUCE INFORMATION FOR INCOMPATIBILITY OF CONCOMITANT ADMINISTRATION WITH AMPICILLIN AND FOSPHENYTOIN. CONSEQUENTLY, THE PACKAGE LEAFLET HAS BEEN UPDATED. **PIL TEXT ONLY HAS BEEN SUPPLIED; THIS HAS BEEN RE-INDEXED TO THE INPUT FOLDER AS 'FINAL UK PIL TEXT'. PIL MOCK-UPS HAVE BEEN APPROVED SEPARATELY AS PART OF A 61(3) NOTIFICATION (COLLECTION ID 215154; GRANTED 23/08/2019).**
PL 00116/0643	TRIOMEL 7 G/L NITROGEN 1140 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0643-0064	PL 00116/0643-0064	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

										IN ADDITION, THE PRODUCT CCDS HAS BEEN UPDATED TO INTRODUCE INFORMATION FOR INCOMPATIBILITY OF CONCOMITANT ADMINISTRATION WITH AMPICILLIN AND FOSPHENYTOIN. CONSEQUENTLY, THE PACKAGE LEAFLET HAS BEEN UPDATED. **PIL TEXT ONLY HAS BEEN SUPPLIED; THIS HAS BEEN RE-INDEXED TO THE INPUT FOLDER AS 'FINAL UK PIL TEXT'. PIL MOCK-UPS HAVE BEEN APPROVED SEPARATELY AS PART OF A 61(3) NOTIFICATION (COLLECTION ID 215154; GRANTED 23/08/2019).**
PL 00116/0643	TRIOMEL 7 G/L NITROGEN 1140 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0643-0064	PL 00116/0643-0064	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

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PL 00116/0643	TRIOMEL 7 G/L NITROGEN 1140 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0643-0064	PL 00116/0643-0064	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

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PL 00116/0644	TRIOMEL 7 G/L NITROGEN 1140 KCAL/L, EMULSION FOR INFUSION	GRANTED	PL 00116/0644-0058	PL 00116/0644-0058	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

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PL 00116/0644	TRIOMEL 7 G/L NITROGEN 1140 KCAL/L, EMULSION FOR INFUSION	GRANTED	PL 00116/0644-0058	PL 00116/0644-0058	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

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PL 00116/0644	TRIOMEL 7 G/L NITROGEN 1140 KCAL/L, EMULSION FOR INFUSION	GRANTED	PL 00116/0644-0058	PL 00116/0644-0058	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

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PL 00116/0645	TRIOMEL 9 G/L NITROGEN 1070 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0645-0064	PL 00116/0645-0064	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

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PL 00116/0645	TRIOMEL 9 G/L NITROGEN 1070 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0645-0064	PL 00116/0645-0064	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

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PL 00116/0645	TRIOMEL 9 G/L NITROGEN 1070 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0645-0064	PL 00116/0645-0064	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

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PL 00116/0646	TRIOMEL 9 G/L NITROGEN 1070 KCAL/L, EMULSION FOR INFUSION	GRANTED	PL 00116/0646-0057	PL 00116/0646-0057	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

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PL 00116/0646	TRIOMEL 9 G/L NITROGEN 1070 KCAL/L, EMULSION FOR INFUSION	GRANTED	PL 00116/0646-0057	PL 00116/0646-0057	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

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PL 00116/0646	TRIOMEL 9 G/L NITROGEN 1070 KCAL/L, EMULSION FOR INFUSION	GRANTED	PL 00116/0646-0057	PL 00116/0646-0057	11/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.7, 4.8, 4.9 AND 6.2 OF THE SPC AS PER RECOMMENDATIONS FROM PBRER ASSESSMENT.

										IN ADDITION, THE PRODUCT CCDS HAS BEEN UPDATED TO INTRODUCE INFORMATION FOR INCOMPATIBILITY OF CONCOMITANT ADMINISTRATION WITH AMPICILLIN AND FOSPHENYTOIN. CONSEQUENTLY, THE PACKAGE LEAFLET HAS BEEN UPDATED. **PIL TEXT ONLY HAS BEEN SUPPLIED; THIS HAS BEEN RE-INDEXED TO THE INPUT FOLDER AS 'FINAL UK PIL TEXT'. PIL MOCK-UPS HAVE BEEN APPROVED SEPARATELY AS PART OF A 61(3) NOTIFICATION (COLLECTION ID 215154; GRANTED 23/08/2019).**
PL 00116/0641	TRIOMEL PERIPHERAL 4 G/L NITROGEN 700 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0641-0077	PL 00116/0641-0077	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR).

										[2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH.

										TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0641	TRIOMEL PERIPHERAL 4 G/L NITROGEN 700 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0641-0077	PL 00116/0641-0077	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR). [2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF

										HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH. TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0642	TRIOMEL 5 G/L NITROGEN 990 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0642-0074	PL 00116/0642-0074	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION

								CMS WORKSHARING		GUIDELINES (ESPGHAN/ESPEN/ESPR). [2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE

										SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH. TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0642	TRIOMEL 5 G/L NITROGEN 990 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0642-0074	PL 00116/0642-0074	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR). [2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION

										RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH. TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 00116/0643	TRIOMEL 7 G/L NITROGEN 1140 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0643-0075	PL 00116/0643-0075	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR). [2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED

										DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH. TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0643	TRIOMEL 7 G/L NITROGEN 1140 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0643-0075	PL 00116/0643-0075	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR). [2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND

										OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH. TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1).

										CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0644	TRIOMEL 7 G/L NITROGEN 1140 KCAL/L, EMULSION FOR INFUSION	GRANTED	PL 00116/0644-0064	PL 00116/0644-0064	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR). [2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED.

										[3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH. TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0644	TRIOMEL 7 G/L NITROGEN 1140 KCAL/L, EMULSION FOR INFUSION	GRANTED	PL 00116/0644-0064	PL 00116/0644-0064	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR). [2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION

										PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH. TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1).

										CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0645	TRIOMEL 9 G/L NITROGEN 1070 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0645-0075	PL 00116/0645-0075	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR). [2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY

										DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH. TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0645	TRIOMEL 9 G/L NITROGEN 1070 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0645-0075	PL 00116/0645-0075	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR). [2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO

										ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH. TO ALSO MAKE MINOR

										REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0646	TRIOMEL 9 G/L NITROGEN 1070 KCAL/L, EMULSION FOR INFUSION	GRANTED	PL 00116/0646-0063	PL 00116/0646-0063	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR). [2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL

										NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH. TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00116/0646	TRIOMEL 9 G/L NITROGEN 1070 KCAL/L, EMULSION FOR INFUSION	GRANTED	PL 00116/0646-0063	PL 00116/0646-0063	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTION 4.2 OF THE SMPC IN LINE WITH THE PARENTERAL NUTRITION GUIDELINES (ESPGHAN/ESPEN/ESPR).

										[2] TO UPDATE SECTION 4.4 OF THE SMPC IN ORDER TO ALIGN TO OTHER PARENTERAL NUTRITION PRODUCTS (CLINOLEIC FR/H/0115/II/25/G AND OLIMEL N12E/N12 FR/H/0419/007-008) AND TO BETTER REFLECT THE SAFETY INFORMATION RELATED TO THE POTENTIAL DEVELOPMENT OF HEPATOBILIARY DISORDERS IN PATIENTS ON PARENTERAL NUTRITION A WARNING FOR HEPATOBILIARY DISORDERS IS PROPOSED. [3] TO UPDATE SECTION 4.5 OF THE SMPC AS REQUESTED DURING PROCEDURE FR/H/0419/007-008. [4] TO UPDATE SECTION 4.8 OF THE SMPC TO ADD TWO ADVERSE REACTIONS - VOMITING AND RASH.

										TO ALSO MAKE MINOR REVISIONS TO THE SPC (SECTIONS 2, 4.3, 4.6, 5.1, 6.1). CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 17780/0017	ZOLPIDEM TARTRATE 5MG TABLETS	GRANTED	PL 17780/0017-0080	PL 17780/0017-0080	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND PILL AS REQUESTED BY THE CMDH IN APRIL 2018 AND IN ORDER TO HAVE AN HARMONIZED APPROACH IN ALL EU MEMBER STATES SMPC, IN SANOFI PRODUCTS.
PL 17780/0018	ZOLPIDEM TARTRATE 10MG TABLETS	GRANTED	PL 17780/0018-0083	PL 17780/0018-0083	12/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND PILL AS REQUESTED BY THE CMDH IN APRIL 2018 AND IN ORDER TO HAVE AN HARMONIZED APPROACH IN ALL EU MEMBER STATES SMPC, IN SANOFI PRODUCTS.
PL 00038/0368	AUGMENTIN 1G TABLETS	GRANTED	PL 00038/0368-0095	PL 00038/0368-0095	13/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO REGISTER VERSION 2.4 OF THE EU-RISK MANAGEMENT PLAN (RMP).

								CMS WORKSHARING		
PL 11587/0036	VINORELBINE 10 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 11587/0036-0031	PL 11587/0036-0031	15/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO CONDUCT MINOR FORMATTING AND EDITORIAL CHANGES IN THE SMPC AND PIL OF PROCEDURE DK/H/0907/001/MR.
PL 20692/0163	COMBOGESIC 500 MG/150 MG FILM-COATED TABLETS	GRANTED	PL 20692/0163-0004	PL 20692/0163-0004	22/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE RISK MANAGEMENT PLAN FOR THE MAHS VALE PHARMACEUTICALS LIMITED, AND TO REGISTER THE RMP FOR SWIXX.
PL 00063/0097	GAVISCON ADVANCE SUSPENSION	GRANTED	PL 00063/0097-0086	PL 00063/0097-0086	26/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 2-0 (IN PL 00063/0144 ONLY), 4-4, 4-5, 4-8, 4-9 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET AND THE EXCIPIENT GUIDELINE.
PL 00063/0103	GAVISCON ADVANCE - PEPPERMINT FLAVOUR	GRANTED	PL 00063/0103-0062	PL 00063/0103-0062	26/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 2-0 (IN PL 00063/0144 ONLY), 4-4, 4-5, 4-8, 4-9 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET AND THE EXCIPIENT GUIDELINE.
PL 00063/0112	GAVISCON ADVANCE LIQUID SACHETS	GRANTED	PL 00063/0112-0063	PL 00063/0112-0063	26/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SMPC SECTIONS 2-0 (IN PL 00063/0144 ONLY), 4-4, 4-5, 4-8, 4-9 AND PIL IN

								RD) - CMS GROUPIN G		LINE WITH THE COMPANY CORE DATA SHEET AND THE EXCIPIENT GUIDELINE.
PL 00063/0 144	GAVISCON ADVANCE TABLETS	GRAN TED	PL 00063/0 144- 0044	PL 00063/0 144- 0044	26/08/ 2020	VARIA TION	TYPE II	VARV MEDICAL TYPE II (STANDA RD) - CMS GROUPIN G	MUTUAL RECOGNI TION	TO UPDATE SMPC SECTIONS 2-0 (IN PL 00063/0144 ONLY), 4-4, 4-5, 4-8, 4-9 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET AND THE EXCIPIENT GUIDELINE.
PL 17907/0 384	ESOMEPRAZOLE 20 MG GASTRO- RESISTANT TABLETS	GRAN TED	PL 17907/0 384- 0017	PL 17907/0 384- 0017	26/08/ 2020	VARIA TION	TYPE II	VARV MEDICAL TYPE II (STANDA RD) - CMS	MUTUAL RECOGNI TION	TO UPDATE RISK MANAGEMENT PLAN FOR - ESOMEPRAZOLE (AS MAGNESIUM DIHYDRATE)20MG, & 40MG GASTRO- RESISTANT TABLETS.
PL 17907/0 385	ESOMEPRAZOLE 40 MG GASTRO- RESISTANT TABLETS	GRAN TED	PL 17907/0 385- 0017	PL 17907/0 385- 0017	26/08/ 2020	VARIA TION	TYPE II	VARV MEDICAL TYPE II (STANDA RD) - CMS	MUTUAL RECOGNI TION	TO UPDATE RISK MANAGEMENT PLAN FOR - ESOMEPRAZOLE (AS MAGNESIUM DIHYDRATE)20MG, & 40MG GASTRO- RESISTANT TABLETS.
PL 44696/0 009	OTIGO 40 MG/10 MG/G EAR DROPS, SOLUTION	GRAN TED	PL 44696/0 009- 0004	PL 44696/0 009- 0004	27/08/ 2020	VARIA TION	TYPE II	VARV MEDICAL TYPE II (STANDA RD) - CMS	MUTUAL RECOGNI TION	(1)TO UPDATE THE CHANGES TO HUMAN AND VETERINARY MEDICINAL PRODUCTS IN ORDER TO UPDATE THE PRODUCT INFORMATION- FULFILMENT OF

										COMMITMENT IN RUP PROCEDURE. (2) TO CHANGE THE OBLIGATIONS AND CONDITIONS OF THE MARKETING AUTHORISATION, INCLUDING THE RISK MANAGEMENT PLAN (3) TO UPDATE SECTIONS 4.2, 4.4, 4.6, 4.8, 5.2, 6.5, 6.6 AND 7 OF THE SPC.
PL 44696/0009	OTIGO 40 MG/10 MG/G EAR DROPS, SOLUTION	GRANTED	PL 44696/0009-0004	PL 44696/0009-0004	27/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	(1)TO UPDATE THE CHANGES TO HUMAN AND VETERINARY MEDICINAL PRODUCTS IN ORDER TO UPDATE THE PRODUCT INFORMATION-FULFILMENT OF COMMITMENT IN RUP PROCEDURE. (2) TO CHANGE THE OBLIGATIONS AND CONDITIONS OF THE MARKETING AUTHORISATION, INCLUDING THE RISK MANAGEMENT PLAN (3) TO UPDATE SECTIONS 4.2, 4.4, 4.6, 4.8, 5.2, 6.5, 6.6 AND 7 OF THE SPC.

PL 30684/0133	ETORICOXIB 30 MG FILM-COATED TABLETS	GRANTED	PL 30684/0133-0003	PL 30684/0133-0003	27/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP IN LINE WITH GVP MODULE V, REVISION.
PL 30684/0134	ETORICOXIB 60 MG FILM-COATED TABLETS	GRANTED	PL 30684/0134-0003	PL 30684/0134-0003	27/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP IN LINE WITH GVP MODULE V, REVISION.
PL 30684/0135	ETORICOXIB 90 MG FILM-COATED TABLETS	GRANTED	PL 30684/0135-0003	PL 30684/0135-0003	27/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP IN LINE WITH GVP MODULE V, REVISION.
PL 30684/0136	ETORICOXIB 120 MG FILM-COATED TABLETS	GRANTED	PL 30684/0136-0003	PL 30684/0136-0003	27/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP IN LINE WITH GVP MODULE V, REVISION.
PL 20117/0163	METHOTREXATE 2.5 MG TABLETS	GRANTED	PL 20117/0163-0040	PL 20117/0163-0040	31/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE RMP INCLUDING THE FOLLOWING ADDITIONAL RISK MINIMISATION MEASURES TO ADDRESS THE IMPORTANT IDENTIFIED RISK OF MEDICATION ERRORS RESULTING IN OVERDOSE:

										- EDUCATIONAL MATERIAL(S) FOR HEALTHCARE PROFESSIONALS DEVELOPED IN ACCORDANCE WITH THE KEY ELEMENTS AGREED; - THE AGREED PATIENT CARD
PL 20117/0172	METHOTREXATE 10 MG TABLETS	GRANTED	PL 20117/0172-0032	PL 20117/0172-0032	31/08/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE RMP INCLUDING THE FOLLOWING ADDITIONAL RISK MINIMISATION MEASURES TO ADDRESS THE IMPORTANT IDENTIFIED RISK OF MEDICATION ERRORS RESULTING IN OVERDOSE: - EDUCATIONAL MATERIAL(S) FOR HEALTHCARE PROFESSIONALS DEVELOPED IN ACCORDANCE WITH THE KEY ELEMENTS AGREED; - THE AGREED PATIENT CARD

PL 04569/0549	OFLOXACIN 200MG TABLETS	GRANTED	PL 04569/0549-0051	PL 04569/0549-0051	01/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC FRAGMENTS OF PRODUCT INFORMATION OFOFLOXACIN TABLETS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 (CMDH 132/2009/REV 55) DATED FEBRUARY 2020. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04569/0550	OFLOXACIN 400MG TABLETS	GRANTED	PL 04569/0550-0059	PL 04569/0550-0059	01/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC FRAGMENTS OF PRODUCT INFORMATION OFOFLOXACIN TABLETS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 (CMDH 132/2009/REV 55) DATED FEBRUARY 2020. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 46302/0001	ARYTHMOL 150MG TABLETS	GRANTED	PL 46302/0001-0013	PL 46302/0001-0013	03/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.9 TO BRING THE WORDING IN LINE WITH THE CCDS WHICH HAS BEEN

								CMS WORKSHARING		RECENTLY UPDATED: 1) NEW CLINICAL DATA: INTERNAL SAFETY SIGNAL DETECTION ON ¿OVERDOSE-RELATED CARDIAC ARREST¿. AND 2)NEW CLINICAL DATA: INTERNAL SAFETY SIGNAL DETECTION ON ¿METABOLIC ACIDOSIS¿
PL 46302/0002	ARYTHMOL 300MG TABLETS	GRANTED	PL 46302/0002-0013	PL 46302/0002-0013	03/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.4 AND 4.9 TO BRING THE WORDING IN LINE WITH THE CCDS WHICH HAS BEEN RECENTLY UPDATED: 1) NEW CLINICAL DATA: INTERNAL SAFETY SIGNAL DETECTION ON ¿OVERDOSE-RELATED CARDIAC ARREST¿. AND 2)NEW CLINICAL DATA: INTERNAL SAFETY SIGNAL DETECTION ON ¿METABOLIC ACIDOSIS¿
PL 04416/0707	CALCIPOTRIOL CREAM 50 MICROGRAMS/G	GRANTED	PL 04416/0707-0035	PL 04416/0707-0035	03/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1AND 6.1 OF THE SMPC AND PIL IN LINE TO THE NOT HARMONISED REFERENCE PRODUCT DAIVONEX

										50 MIKROGRAMM/G CREME (CALCIPOTRIOL), LEO PHARMA GMBH, GERMANY, DATED NOVEMBER 2017 AND MINOR EDITORIAL CHANGES AND ADAPTIONS TO THE CURRENT QRD TEMPLATE
PL 33616/0013	EMERADE, 150 MICROGRAMS, SOLUTION FOR INJECTION IN PRE-FILLED PEN	GRANTED	PL 33616/0013-0031	PL 33616/0013-0031	03/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.8 AND 6.6 OF THE SMPC, LABELLING AND PIL FOLLOWING EMA REQUEST AND RMS OPINION O ADD SOME ADDITIONAL INSTRUCTION ON THE USE OF PEN - INFORMATION ABOUT ANGLE OF USE.
PL 33616/0014	EMERADE, 300 MICROGRAMS, SOLUTION FOR INJECTION IN PRE-FILLED PEN	GRANTED	PL 33616/0014-0031	PL 33616/0014-0031	03/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.8 AND 6.6 OF THE SMPC, LABELLING AND PIL FOLLOWING EMA REQUEST AND RMS OPINION O ADD SOME ADDITIONAL INSTRUCTION ON THE USE OF PEN - INFORMATION ABOUT ANGLE OF USE.
PL 33616/0015	EMERADE, 500 MICROGRAMS, SOLUTION FOR INJECTION IN PRE-FILLED PEN	GRANTED	PL 33616/0015-0032	PL 33616/0015-0032	03/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.8 AND 6.6 OF THE SMPC, LABELLING AND PIL FOLLOWING EMA REQUEST AND RMS OPINION O ADD

										SOME ADDITIONAL INSTRUCTION ON THE USE OF PEN - INFORMATION ABOUT ANGLE OF USE.
PL 25258/0217	OXYCODONE GLENMARK 5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0217-0027	PL 25258/0217-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0217	RENOCONTIN 5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0217-0027	PL 25258/0217-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0218	OXYCODONE GLENMARK 10 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0218-0027	PL 25258/0218-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0218	RENOCONTIN 10 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0218-0027	PL 25258/0218-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80

										MG PROLONGED RELEASE TABLETS.
PL 25258/0219	OXYCODONE GLENMARK 15 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0219-0027	PL 25258/0219-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0219	RENOCONTIN 15 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0219-0027	PL 25258/0219-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0220	OXYCODONE GLENMARK 20 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0220-0027	PL 25258/0220-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0220	RENOCONTIN 20 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0220-0027	PL 25258/0220-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.

PL 25258/0221	OXYCODONE GLENMARK 30 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0221-0027	PL 25258/0221-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0221	RENOCONTIN 30 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0221-0027	PL 25258/0221-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0222	OXYCODONE GLENMARK 40 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0222-0027	PL 25258/0222-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0222	RENOCONTIN 40 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0222-0027	PL 25258/0222-0027	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0223	OXYCODONE GLENMARK 60 MG	GRANTED	PL 25258/0	PL 25258/0	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE

	PROLONGED-RELEASE TABLETS		223-0025	223-0025				(STANDARD) - CMS		REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0223	RENOCONTIN 60 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0223-0025	PL 25258/0223-0025	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0224	OXYCODONE GLENMARK 80 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0224-0026	PL 25258/0224-0026	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 25258/0224	RENOCONTIN 80 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 25258/0224-0026	PL 25258/0224-0026	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT TEXT FOR UK: OXYCONTIN 5, 10, 15, 20, 30, 40, 60, 80 MG PROLONGED RELEASE TABLETS.
PL 01656/0005	LANSOPRAZOLE 15 MG GASTRO-RESISTANT CAPSULES	GRANTED	PL 01656/0005-0057	PL 01656/0005-0057	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.6, 4.8 AND 5.2 OF THE SMPC AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR

										PHARMACOVIGILANCE DATA. PRODUCT NOT MARKETED.
PL 01656/0006	LANSOPRAZOLE 30 MG GASTRO-RESISTANT CAPSULES	GRANTED	PL 01656/0006-0055	PL 01656/0006-0055	04/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.6, 4.8 AND 5.2 OF THE SMPC AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA. PRODUCT NOT MARKETED.
PL 04416/1247	AZATHIOPRINE 25MG FILM-COATED TABLETS	GRANTED	PL 04416/1247-0037	PL 04416/1247-0037	10/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.6 AND 4.8 OF THE SPC IN REFERENCE PRODUCT IMUREK FILMTABLETTEN, ASPEN PHARMA. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED.
PL 04416/1248	AZATHIOPRINE 50MG FILM-COATED TABLETS	GRANTED	PL 04416/1248-0043	PL 04416/1248-0043	10/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.6 AND 4.8 OF THE SPC IN REFERENCE PRODUCT IMUREK FILMTABLETTEN, ASPEN PHARMA. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED.
PL 04416/0609	CLARITHROMYCIN 125MG/5ML SUSPENSION	GRANTED	PL 04416/0	PL 04416/0	10/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6, 4.8 AND 6.6 OF THE SPC

			609-0069	609-0069				(STANDARD) - CMS		IN LINE WITH THE MOST CURRENT SCIENTIFIC DATA AS PER KLACID LA 500MG MODIFIED RELEASE TABLETS (MYLAN IRE HEALTHCARE LIMITED). CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED. ADDITIONALLY, TO IMPLEMENT 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). CONSEQUENTLY, THE LABELLING HAS ALSO BEEN UPDATED.
PL 04416/0610	CLARITHROMYCIN 250MG/5ML SUSPENSION	GRANTED	PL 04416/0610-0069	PL 04416/0610-0069	10/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4, 4.5, 4.6, 4.8 AND 6.6 OF THE SPC IN LINE WITH THE MOST CURRENT SCIENTIFIC DATA AS

										PER KLACID LA 500MG MODIFIED RELEASE TABLETS (MYLAN IRE HEALTHCARE LIMITED). CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED. ADDITIONALLY, TO IMPLEMENT 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). CONSEQUENTLY, THE LABELLING HAS ALSO BEEN UPDATED.
PL 35104/0019	BENZYDAMINE 0.15% W/V OROMUCOSAL SPRAY	GRANTED	PL 35104/0019-0013	PL 35104/0019-0013	11/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.8 OF THE SMPC AND PIL FOLLOWING PROCEDURE WITH THE AGREED CHANGES MADE TO THE IRISH SPC

										DURING THE PROCEDURE.
PL 00116/0648	NUMETA G16%E, EMULSION FOR INFUSION	GRANTED	PL 00116/0648-0066	PL 00116/0648-0066	14/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE SPC (2, 4.2, 4.4, 6.1, 6.2, 6.3, 6.5, 6.6) IN LINE WITH THE RECOMMENDATIONS ADOPTED BY THE PRAC RECOMMENDATIONS ON SIGNALS EMA/PRAC/347675/2019 WHERE APPLICABLE, AND TO RECTIFY TYPOGRAPHICAL ERRORS NOTED IN THE PRODUCT INFORMATION FOLLOWING THE CONCLUSION OF VARIATION REFERENCE SE/H/0918/002-004/035/G. CONSEQUENTIALLY, THE PIL AND LABEL ARE ALSO UPDATED.
PL 00116/0649	NUMETA G19 E, EMULSION FOR INFUSION	GRANTED	PL 00116/0649-0060	PL 00116/0649-0060	14/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE SPC (2, 4.2, 4.4, 6.1, 6.2, 6.3, 6.5, 6.6) IN LINE WITH THE RECOMMENDATIONS ADOPTED BY THE PRAC RECOMMENDATIONS ON SIGNALS EMA/PRAC/347675/201

										9 WHERE APPLICABLE, AND TO RECTIFY TYPOGRAPHICAL ERRORS NOTED IN THE PRODUCT INFORMATION FOLLOWING THE CONCLUSION OF VARIATION REFERENCE SE/H/0918/002-004/035/G. CONSEQUENTIALLY, THE PIL AND LABEL ARE ALSO UPDATED.
PL 00116/0659	NUMETA G13%E PRETERM	GRANTED	PL 00116/0659-0022	PL 00116/0659-0022	14/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE SPC (2, 4.2, 4.4, 6.1, 6.2, 6.3, 6.5, 6.6) IN LINE WITH THE RECOMMENDATIONS ADOPTED BY THE PRAC RECOMMENDATIONS ON SIGNALS EMA/PRAC/347675/2019 WHERE APPLICABLE, AND TO RECTIFY TYPOGRAPHICAL ERRORS NOTED IN THE PRODUCT INFORMATION FOLLOWING THE CONCLUSION OF VARIATION REFERENCE SE/H/0918/002-004/035/G.

										CONSEQUENTIALLY, THE PIL AND LABEL ARE ALSO UPDATED.
PL 00116/0662	TRIOMEL 12 G/L NITROGEN 950 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0662-0009	PL 00116/0662-0009	15/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8, 5.1, 6.1 AND 6.6 OF THE SPC DUE TO NEW QUALITY, PRECLINICAL OR PHARMACOVIGILANCE DATA. CONSEQUENTIALLY, THE LABELLING AND LEAFLET ARE ALSO UPDATED.
PL 00116/0662	TRIOMEL 12 G/L NITROGEN 950 KCAL/L WITH ELECTROLYTES, EMULSION FOR INFUSION	GRANTED	PL 00116/0662-0009	PL 00116/0662-0009	15/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8, 5.1, 6.1 AND 6.6 OF THE SPC DUE TO NEW QUALITY, PRECLINICAL OR PHARMACOVIGILANCE DATA. CONSEQUENTIALLY, THE LABELLING AND LEAFLET ARE ALSO UPDATED.
PL 00116/0663	TRIOMEL 12 G/L NITROGEN 950 KCAL/L EMULSION FOR INFUSION	GRANTED	PL 00116/0663-0006	PL 00116/0663-0006	15/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.8, 5.1, 6.1 AND 6.6 OF THE SMPC AND PIL: 1) TO GIVE RECOMMENDATION FOR THE SPECIFIC INFUSION RATE IN PATIENTS ON IDPN. 2) TO REMOVE THE PARAGRAPH FOR MEASUREMENT OF

										OSMOLARITY OF OLIMEL WITH ADDITIONS BEFORE PERIPHERAL ADMINISTRATIONS. 3) IN POST-MARKETING EXPERIENCE TWO ADVERSE REACTIONS HAVE BEEN REPORTED ASSOCIATED WITH OLIMEL ADMINISTRATION: VOMITING AND RASH. THESE ARE THEREFORE PROPOSED FOR ADDITION TO SECTION 4.8.
PL 00116/0663	TRIOMEL 12 G/L NITROGEN 950 KCAL/L EMULSION FOR INFUSION	GRANTED	PL 00116/0663-0006	PL 00116/0663-0006	15/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.8, 5.1, 6.1 AND 6.6 OF THE SMPC AND PIL: 1) TO GIVE RECOMMENDATION FOR THE SPECIFIC INFUSION RATE IN PATIENTS ON IDPN. 2) TO REMOVE THE PARAGRAPH FOR MEASUREMENT OF OSMOLARITY OF OLIMEL WITH ADDITIONS BEFORE PERIPHERAL

										ADMINISTRATIONS. 3) IN POST-MARKETING EXPERIENCE TWO ADVERSE REACTIONS HAVE BEEN REPORTED ASSOCIATED WITH OLIMEL ADMINISTRATION: VOMITING AND RASH. THESE ARE THEREFORE PROPOSED FOR ADDITION TO SECTION 4.8.
PL 16950/0084	ZAMADOL 24HR 150MG PROLONGED RELEASE TABLETS	GRANTED	PL 16950/0084-0086	PL 16950/0084-0086	15/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) OF OPIOID PRODUCTS, INCLUDING THE TRAMADOL HYDROCHLORIDE CCDS: ·SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND

										·SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.
PL 16950/0085	ZAMADOL 24HR 200MG PROLONGED RELEASE TABLETS	GRANTED	PL 16950/0085-0083	PL 16950/0085-0083	15/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) OF OPIOID PRODUCTS, INCLUDING THE TRAMADOL HYDROCHLORIDE CCDS: ·SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND ·SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.
PL 16950/0086	ZAMADOL 24HR 300MG PROLONGED RELEASE TABLETS	GRANTED	PL 16950/0086-0082	PL 16950/0086-0082	15/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) OF OPIOID PRODUCTS, INCLUDING THE

								RD) - CMS		TRAMADOL HYDROCHLORIDE CCDS: ·SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND ·SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.
PL 16950/0087	ZAMADOL 24HR 400MG PROLONGED RELEASE TABLETS	GRANTED	PL 16950/0087-0083	PL 16950/0087-0083	15/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) OF OPIOID PRODUCTS, INCLUDING THE TRAMADOL HYDROCHLORIDE CCDS: ·SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP

										BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND ·SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.
PL 42467/0001	PENTHROX 99.9%, 3 ML INHALATION VAPOUR, LIQUID	GRANTED	PL 42467/0001-0037	PL 42467/0001-0037	16/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO AN UPDATE TO SECTIONS 4.2, 4.5 , 4.6, 4.8 , 4.9, 5.2 AND 5.3 OF THE SUMMARY OF PRODUCT CHARACTERISTICS (SPC) AND PACKAGE LEAFLET (PL) FOLLOWING THE REVIEW OF THE COMPANY CORE DATA SHEET (CCDS) FOR PENTHROX 99.9%, 3 ML INHALATION VAPOUR, LIQUID, (IE/H/0828/001/DC).
PL 36390/0232	LENALIDOMIDE 5 MG CAPSULES HARD	GRANTED	PL 36390/0232-0004	PL 36390/0232-0004	19/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.6, 4.8 AND 5.1 OF THE SMPC AND PIL ACCORDING TO CMDH/CMDV/132/2009, REV.54 SEPTEMBER 2019 - Q&A - LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO

										COMMISSION REGULATION (EC) 1234/2008 -
PL 36390/0233	LENALIDOMIDE 10 MG CAPSULES HARD	GRANTED	PL 36390/0233-0005	PL 36390/0233-0005	19/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.6, 4.8 AND 5.1 OF THE SMPC AND PIL ACCORDING TO CMDH/CMDV/132/2009, REV.54 SEPTEMBER 2019 - Q&A - LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 -
PL 36390/0234	LENALIDOMIDE 15 MG CAPSULES HARD	GRANTED	PL 36390/0234-0004	PL 36390/0234-0004	19/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.6, 4.8 AND 5.1 OF THE SMPC AND PIL ACCORDING TO CMDH/CMDV/132/2009, REV.54 SEPTEMBER 2019 - Q&A - LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 -
PL 36390/0235	LENALIDOMIDE 20 MG CAPSULES HARD	GRANTED	PL 36390/0235-0004	PL 36390/0235-0004	19/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.6, 4.8 AND 5.1 OF THE SMPC AND PIL ACCORDING TO CMDH/CMDV/132/2009, REV.54 SEPTEMBER 2019 - Q&A - LIST FOR

										THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 -
PL 36390/0236	LENALIDOMIDE 25 MG CAPSULES HARD	GRANTED	PL 36390/0236-0004	PL 36390/0236-0004	19/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.6, 4.8 AND 5.1 OF THE SMPC AND PIL ACCORDING TO CMDH/CMDV/132/2009, REV.54 SEPTEMBER 2019 - Q&A - LIST FOR THE SUBMISSION OF VARIATIONS ACCORDING TO COMMISSION REGULATION (EC) 1234/2008 -
PL 50622/0018	EFEXOR XL 150MG CAPSULES	GRANTED	PL 50622/0018-0005	PL 50622/0018-0005	21/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.8 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS) TO INCLUDE INFORMATION REGARDING THE DISCONTINUATION OF TREATMENT WITH VENLAFAXINE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 50622/0019	EFEXOR XL 225 MG HARD PROLONGED-RELEASE CAPSULES	GRANTED	PL 50622/0019-0004	PL 50622/0019-0004	21/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.8 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET

								CMS WORKSHARING		(CCDS) TO INCLUDE INFORMATION REGARDING THE DISCONTINUATION OF TREATMENT WITH VENLAFAXINE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 50622/0020	EFEXOR XL 75MG CAPSULES	GRANTED	PL 50622/0020-0005	PL 50622/0020-0005	21/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4 AND 4.8 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS) TO INCLUDE INFORMATION REGARDING THE DISCONTINUATION OF TREATMENT WITH VENLAFAXINE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 20075/0076	LETROZOLE 2.5MG FILM-COATED TABLETS	GRANTED	PL 20075/0076-0035	PL 20075/0076-0035	22/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE THE RISK MANAGEMENT PLANT (RMP) FOR LETROZOLE 2.5 MG FILM-COATED TABLETS.
PL 17901/0201	CRESTOR 10MG FILM-COATED TABLETS	GRANTED	PL 17901/0201-0145	PL 17901/0201-0145	23/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3 AND 4.5 OF THE SMPC AND PIL TO ALIGN WITH THE LATEST CORE DATA SHEET (CDS) DATED DECEMBER 2019.

PL 17901/0202	CRESTOR 20MG FILM-COATED TABLETS	GRANTED	PL 17901/0202-0142	PL 17901/0202-0142	23/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3 AND 4.5 OF THE SMPC AND PIL TO ALIGN WITH THE LATEST CORE DATA SHEET (CDS) DATED DECEMBER 2019.
PL 17901/0203	CRESTOR 40MG FILM-COATED TABLETS	GRANTED	PL 17901/0203-0140	PL 17901/0203-0140	23/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3 AND 4.5 OF THE SMPC AND PIL TO ALIGN WITH THE LATEST CORE DATA SHEET (CDS) DATED DECEMBER 2019.
PL 17901/0243	CRESTOR 5MG FILM-COATED TABLETS	GRANTED	PL 17901/0243-0136	PL 17901/0243-0136	23/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3 AND 4.5 OF THE SMPC AND PIL TO ALIGN WITH THE LATEST CORE DATA SHEET (CDS) DATED DECEMBER 2019.
PL 04416/0707	CALCIPOTRIOL CREAM 50 MICROGRAMS/G	GRANTED	PL 04416/0707-0023	PL 04416/0707-0023	29/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SECTIONS 4.2 - 4.4, 4.6 - 4.8 AND 5.3 OF THE SPC IN LINE WITH THE RECENTLY UPDATED SANDOZ CORE COMPANY DATA SHEET, CALCIPOTRIOL_TOPICAL_04_2013. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.

PL 04569/1756	BRABIO 40MG/ML SOLUTION FOR INJECTION, PRE-FILLED SYRINGE	GRANTED	PL 04569/1756-0009	PL 04569/1756-0009	29/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 3, 4.2, 4.3, 4.4, 4.6, 4.8, 4.9, 5.1 AND 5.3 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, COPAXONE 40 MG/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE (PL 10921/0026 - MAH: TEVA PHARMACEUTICALS LTD.). ADDITIONAL MINOR EDITORIAL UPDATES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 11906/0007	RUPAFIN 10MG TABLETS	GRANTED	PL 11906/0007-0057	PL 11906/0007-0057	29/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 1, 2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC AS A CONSEQUENCE PACKAGE LEAFLET DUE TO ADDITIONAL INTERACTION STUDIES THAT WERE CONDUCTED ON RUPATADINE.
PL 11906/0009	RUPATADINE 1 MG/ML ORAL SOLUTION	GRANTED	PL 11906/0009-0038	PL 11906/0009-0038	29/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTION 1, 2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 AND 5.3 OF THE SPC AS A

								RD) - CMS		CONSEQUENCE PACKAGE LEAFLET DUE TO ADDITIONAL INTERACTION STUDIES THAT WERE CONDUCTED ON RUPATADINE.
PL 04416/0700	CALCIPOTRIOL OINTMENT 50MICROGRAMS/G	GRANTED	PL 04416/0700-0048	PL 04416/0700-0048	30/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.4, 4.6, 4.8 AND 4.9 OF THE SMPC AND PIL TO THE NOT HARMONISED REFERENCE PRODUCT DAIVONEX® 50 MIKROGRAMM/G CREME (CALCIPOTRIOL), LEO PHARMA GMBH, GERMANY, DATED NOVEMBER 2017
PL 04416/0888	CALCIPOTRIOL 50 MICROGRAMS/ML SCALP SOLUTION	GRANTED	PL 04416/0888-0027	PL 04416/0888-0027	30/09/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.4, 4.8 AND 4.9 OF THE SMPC FRAGMENTS IN ADAPTATION TO THE NOT HARMONISED REFERENCE PRODUCT DAIVONEX® 50 MIKROGRAMM/G CREME (CALCIPOTRIOL), LEO PHARMA GMBH, GERMANY, DATED NOVEMBER 2017. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.

PL 17907/0558	ALIVIO 5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17907/0558-0019	PL 17907/0558-0019	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE AN UPDATED RISK MANAGEMENT PLAN FOR ALIVIO 5MG, 10MG, 20MG, 30MG, 40MG, 60MG & 80MG PROLONGED-RELEASE TABLETS.
PL 17907/0559	ALIVIO 10 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17907/0559-0020	PL 17907/0559-0020	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE AN UPDATED RISK MANAGEMENT PLAN FOR ALIVIO 5MG, 10MG, 20MG, 30MG, 40MG, 60MG & 80MG PROLONGED-RELEASE TABLETS.
PL 17907/0560	ALIVIO 20 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17907/0560-0020	PL 17907/0560-0020	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE AN UPDATED RISK MANAGEMENT PLAN FOR ALIVIO 5MG, 10MG, 20MG, 30MG, 40MG, 60MG & 80MG PROLONGED-RELEASE TABLETS.
PL 17907/0561	ALIVIO 30 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17907/0561-0020	PL 17907/0561-0020	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE AN UPDATED RISK MANAGEMENT PLAN FOR ALIVIO 5MG, 10MG, 20MG, 30MG, 40MG, 60MG & 80MG PROLONGED-RELEASE TABLETS.
PL 17907/0562	ALIVIO 40 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17907/0562-0020	PL 17907/0562-0020	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE AN UPDATED RISK MANAGEMENT PLAN FOR ALIVIO 5MG, 10MG, 20MG, 30MG, 40MG, 60MG & 80MG

										PROLONGED-RELEASE TABLETS.
PL 17907/0563	ALIVIO 60 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17907/0563-0020	PL 17907/0563-0020	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE AN UPDATED RISK MANAGEMENT PLAN FOR ALIVIO 5MG, 10MG, 20MG, 30MG, 40MG, 60MG & 80MG PROLONGED-RELEASE TABLETS.
PL 17907/0564	ALIVIO 80 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 17907/0564-0020	PL 17907/0564-0020	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE AN UPDATED RISK MANAGEMENT PLAN FOR ALIVIO 5MG, 10MG, 20MG, 30MG, 40MG, 60MG & 80MG PROLONGED-RELEASE TABLETS.
PL 03194/0125	VITAROS 3 MG/G CREAM	GRANTED	PL 03194/0125-0032	PL 03194/0125-0032	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE PASS DESIGN. BASED ON THE OUTCOME OF THE ADVICE, FERRING UPDATED THE PROTOCOL OUTLINE.
PL 03194/0124	VITAROS 2 MG/G CREAM	GRANTED	PL 03194/0124-0017	PL 03194/0124-0017	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE PASS DESIGN. BASED ON THE OUTCOME OF THE ADVICE, FERRING UPDATED THE PROTOCOL OUTLINE.
PL 04416/1316	PROPOFOL 10 MG/ML (1%) EMULSION FOR INJECTION/INFUSION	GRANTED	PL 04416/1316-0024	PL 04416/1316-0024	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	DECENTRALISED	TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6 AND 4.8 OF THE SPC FOR 10 MG/ML AND 20

								RD) - CMS		MG/ML PRODUCTS IN LINE WITH THE REFERENCE PRODUCT DIPRIVAN-10/DIPRIVAN-20, 10/20 MG/ML EMULSIE VOOR INJECTIE OF INFUSIE, (PROPOFOL), ASPEN PHARMA TRADING LTD., THE NETHERLANDS. CONSEQUENTIALLY THE LEAFLET HAS BEEN UPDATED
PL 04416/1317	PROPOFOL 20 MG/ML (2%) EMULSION FOR INJECTION/INFUSION	GRANTED	PL 04416/1317-0023	PL 04416/1317-0023	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.2, 4.3, 4.4, 4.5, 4.6 AND 4.8 OF THE SPC FOR 10 MG/ML AND 20 MG/ML PRODUCTS IN LINE WITH THE REFERENCE PRODUCT DIPRIVAN-10/DIPRIVAN-20, 10/20 MG/ML EMULSIE VOOR INJECTIE OF INFUSIE, (PROPOFOL), ASPEN PHARMA TRADING LTD., THE NETHERLANDS. CONSEQUENTIALLY THE LEAFLET HAS BEEN UPDATED

PL 00057/0145	FELDENE 10MG CAPSULES	GRANTED	PL 00057/0145-0075	PL 00057/0145-0075	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED.
PL 00057/0146	FELDENE 20MG CAPSULES	GRANTED	PL 00057/0146-0075	PL 00057/0146-0075	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED.
PL 00057/0352	FELDENE MELT 20MG TABLETS	GRANTED	PL 00057/0352-0075	PL 00057/0352-0075	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED.
PL 00057/0931	ARTHROTEC 50 MODIFIED-RELEASE TABLETS	GRANTED	PL 00057/0931-0038	PL 00057/0931-0038	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET. CONSEQUENTLY, THE PATIENT INFORMATION

										LEAFLET HAS ALSO BEEN UPDATED.
PL 00057/0932	ARTHROTEC 75 MODIFIED-RELEASE TABLETS	GRANTED	PL 00057/0932-0045	PL 00057/0932-0045	01/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE COMPANY CORE DATA SHEET. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED.
PL 04569/1348	PERINDOPRIL ERBUMINE 2 MG TABLETS	GRANTED	PL 04569/1348-0026	PL 04569/1348-0026	07/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.3, 4.4, 4.5 AND 4.8 OF THE SMPC ACCORDING TO NEW CLINICAL DATA REGARDING THE INTERNAL SAFETY SIGNAL ON DRUG INTERACTION OF GENERIC ACE INHIBITORS WITH NEPRILYS INHIBITORS RESULTING IN AN INCREASED RISK OF ANGIOEDEMA. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04569/1349	PERINDOPRIL ERBUMINE 4 MG TABLETS	GRANTED	PL 04569/1349-0029	PL 04569/1349-0029	07/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.3, 4.4, 4.5 AND 4.8 OF THE SMPC ACCORDING TO NEW CLINICAL DATA REGARDING THE INTERNAL SAFETY SIGNAL ON DRUG

										INTERACTION OF GENERIC ACE INHIBITORS WITH NEPRILYS INHIBITORS RESULTING IN AN INCREASED RISK OF ANGIOEDEMA. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 04569/1350	PERINDOPRIL ERBUMINE 8 MG TABLETS	GRANTED	PL 04569/1350-0028	PL 04569/1350-0028	07/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.3, 4.4, 4.5 AND 4.8 OF THE SMPC ACCORDING TO NEW CLINICAL DATA REGARDING THE INTERNAL SAFETY SIGNAL ON DRUG INTERACTION OF GENERIC ACE INHIBITORS WITH NEPRILYS INHIBITORS RESULTING IN AN INCREASED RISK OF ANGIOEDEMA. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 16363/0589	FINASTERIDE 5 MG FILM-COATED TABLETS	GRANTED	PL 16363/0589-0013	PL 16363/0589-0013	07/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.6, 4.8, 5.1 OF THE SMPC FRAGMENTS OF THE PRODUCT INFORMATION OF FINASTERIDE AUROBINDO 5 MG FILM-COATED TABLETS IN LINE WITH THE PRODUCT

										INFORMATION OF REFERENCE MEDICINAL PRODUCT I.E. PROSCAR 5 MG FILM-COATED TABLETS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 25258/0278	SOPROBEC 50 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	GRANTED	PL 25258/0278-0006	PL 25258/0278-0006	07/10/2020	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, 4.7, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH COMMENTS MADE BY NEW CMSS DURING A RUP FOR CAPTIONED PRODUCT AND COMMITMENT GIVEN TO SUBMIT POST CLOSURE OF THE RUP VARIATION APPLICATION FOR SAME. CONSEQUENTLY, THE PIL AND LABEL HAVE BEEN UPDATED.
PL 25258/0279	SOPROBEC 100 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	GRANTED	PL 25258/0279-0006	PL 25258/0279-0006	07/10/2020	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, 4.7, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH COMMENTS MADE BY NEW CMSS DURING A RUP FOR CAPTIONED PRODUCT AND COMMITMENT GIVEN TO SUBMIT POST CLOSURE OF THE RUP VARIATION

										APPLICATION FOR SAME. CONSEQUENTLY, THE PIL AND LABEL HAVE BEEN UPDATED.
PL 25258/0280	SOPROBEC 200 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	GRANTED	PL 25258/0280-0006	PL 25258/0280-0006	07/10/2020	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, 4.7, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH COMMENTS MADE BY NEW CMSS DURING A RUP FOR CAPTIONED PRODUCT AND COMMITMENT GIVEN TO SUBMIT POST CLOSURE OF THE RUP VARIATION APPLICATION FOR SAME. CONSEQUENTLY, THE PIL AND LABEL HAVE BEEN UPDATED.
PL 25258/0281	SOPROBEC 250 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	GRANTED	PL 25258/0281-0006	PL 25258/0281-0006	07/10/2020	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, 4.7, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH COMMENTS MADE BY NEW CMSS DURING A RUP FOR CAPTIONED PRODUCT AND COMMITMENT GIVEN TO SUBMIT POST CLOSURE OF THE RUP VARIATION APPLICATION FOR SAME. CONSEQUENTLY, THE PIL AND LABEL HAVE BEEN UPDATED.

PL 10949/0340	ZYBAN 150 MG PROLONGED RELEASE TABLETS	GRANTED	PL 10949/0340-0093	PL 10949/0340-0093	12/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 , 4.5, 4.8 AND 4.9 OF THE SMPC AND PIL FURTHER TO THE FINALISATION OF THE PSUSA PROCEDURE (PSUSA/00000461/201812) AS REQUESTED BY THE MAH OF THE INNOVATOR TO REVIEW OF SEROTONIN SYNDROME.
PL 10592/0162	BOOSTRIX SUSPENSION FOR INJECTION IN PFS	GRANTED	PL 10592/0162-0187	PL 10592/0162-0187	21/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 6.4, 6.5 AND 6.6 OF THE SMPC FRAGMENTS IN ORDER TO UPDATE PRODUCT INFORMATION OF BOOSTRIX AND BOOSTRIX POLIO WITH DATA FROM THREE CLINICAL MATERNAL IMMUNISATION POST-AUTHORISATION SAFETY STUDIES (PASS) (DTPA-047, DTPA-048 PRI AND DTPA-049 BST 048). CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 10592/0162	DIPHTHERIA, TETANUS AND PERTUSSIS (ACELLULAR,	GRANTED	PL 10592/0	PL 10592/0	21/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	DECENTRALISED	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 6.4, 6.5 AND 6.6

	COMPONENT) VACCINE		162-0187	162-0187				(STANDARD) - CMS		OF THE SMPC FRAGMENTS IN ORDER TO UPDATE PRODUCT INFORMATION OF BOOSTRIX AND BOOSTRIX POLIO WITH DATA FROM THREE CLINICAL MATERNAL IMMUNISATION POST-AUTHORISATION SAFETY STUDIES (PASS) (DTPA-047, DTPA-048 PRI AND DTPA-049 BST 048). CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 10592/0214	BOOSTRIX-IPV SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 10592/0214-0229	PL 10592/0214-0229	21/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 6.4, 6.5 AND 6.6 OF THE SMPC FRAGMENTS IN ORDER TO UPDATE PRODUCT INFORMATION OF BOOSTRIX AND BOOSTRIX POLIO WITH DATA FROM THREE CLINICAL MATERNAL IMMUNISATION POST-AUTHORISATION SAFETY STUDIES (PASS) (DTPA-047, DTPA-048 PRI AND DTPA-049 BST 048).

										CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 10592/0214	DIPHTHERIA, TETANUS, PERTUSSIS AND POLIOMYELITIS (INACTIVATED) VACCINE	GRANTED	PL 10592/0214-0229	PL 10592/0214-0229	21/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 6.4, 6.5 AND 6.6 OF THE SMPC FRAGMENTS IN ORDER TO UPDATE PRODUCT INFORMATION OF BOOSTRIX AND BOOSTRIX POLIO WITH DATA FROM THREE CLINICAL MATERNAL IMMUNISATION POST-AUTHORISATION SAFETY STUDIES (PASS) (DTPA-047, DTPA-048 PRI AND DTPA-049 BST 048). CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 00025/0338	COZAAR-COMP 50/12.5 FILM COATED TABLETS	GRANTED	PL 00025/0338-0140	PL 00025/0338-0140	26/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 03, 4.4 AND 4.8 OF THE SMPC, LABELLING AND PIL IN LINE WITH THE PRAC RECOMMENDATION ON SIGNALS FOR THIAZIDE, THIAZIDE-LIKE DIURETIC AND COMBINATION PRODUCTS, WHICH WAS ADOPTED AT THE

										PRAC MEETING ON 09 -12 MARCH 2020 (EPITT NO. 19468)
PL 00025/0374	COZAAR-COMP 100/25 FILM-COATED TABLETS	GRANTED	PL 00025/0374-0106	PL 00025/0374-0106	26/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 03, 4.4 AND 4.8 OF THE SMPC, LABELLING AND PIL IN LINE WITH THE PRAC RECOMMENDATION ON SIGNALS FOR THIAZIDE, THIAZIDE-LIKE DIURETIC AND COMBINATION PRODUCTS, WHICH WAS ADOPTED AT THE PRAC MEETING ON 09 -12 MARCH 2020 (EPITT NO. 19468)
PL 00025/0473	COZAAR-COMP 100 MG/12.5 MG FILM-COATED TABLETS	GRANTED	PL 00025/0473-0077	PL 00025/0473-0077	26/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 03, 4.4 AND 4.8 OF THE SMPC, LABELLING AND PIL IN LINE WITH THE PRAC RECOMMENDATION ON SIGNALS FOR THIAZIDE, THIAZIDE-LIKE DIURETIC AND COMBINATION PRODUCTS, WHICH WAS ADOPTED AT THE PRAC MEETING ON 09 -12 MARCH 2020 (EPITT NO. 19468)
PL 04416/0668	AZITHROMYCIN 500MG TABLETS	GRANTED	PL 04416/0668-0062	PL 04416/0668-0062	26/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 4.9 OF THE SMPC FRAGMENTS IN LINE WITH THE NOT HARMONISED

										REFERENCE PRODUCT ZITHROMAX 250, TABLETTEN 250 MG/ZITHROMAX 500, TABLETTEN 500 MG, PFIZER BV, RVG 19432/ RVG 19432, SEPTEMBER 2019 VIA A TYPE II, CAT. C.I.2.B VARIATION. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04416/0782	AZITHROMYCIN 200MG/5ML POWDER FOR ORAL SUSPENSION	GRANTED	PL 04416/0782-0054	PL 04416/0782-0054	26/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.5, 4.8 AND 4.9 OF THE SMPC FRAGMENTS IN LINE WITH THE NOT HARMONISED REFERENCE PRODUCT ZITHROMAX, SUSPENSIE (POEDER VOOR) 200 MG/5 ML, PFIZER BV, RVG 14999, SEPTEMBER 2019 VIA A TYPE II, CAT. C.I.2.B VARIATION.. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 34926/0001	DYSPORT 500 UNITS POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 34926/0001-0101	PL 34926/0001-0101	28/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE EU RISK MANAGEMENT PLANT (RMP) FOR DYSPORT AND BOTULINUM TOXIN TYPE A-

								WORKSHARING		HAEMAGGLUTININ CONPLEX FROM VERSION 7.0, DATED 27 MARCH 2019 TO VERSION 7.2, DATED 19 FEBRUARY 2020.
PL 34926/0009	BOTULINUM TOXIN TYPE A 500 UNITS POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 34926/0009-0097	PL 34926/0009-0097	28/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE EU RISK MANAGEMENT PLANT (RMP) FOR DYSPORT AND BOTULINUM TOXIN TYPE A-HAEMAGGLUTININ CONPLEX FROM VERSION 7.0, DATED 27 MARCH 2019 TO VERSION 7.2, DATED 19 FEBRUARY 2020.
PL 34926/0014	DYSPORT 300 UNITS POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 34926/0014-0086	PL 34926/0014-0086	28/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE EU RISK MANAGEMENT PLANT (RMP) FOR DYSPORT AND BOTULINUM TOXIN TYPE A-HAEMAGGLUTININ CONPLEX FROM VERSION 7.0, DATED 27 MARCH 2019 TO VERSION 7.2, DATED 19 FEBRUARY 2020.
PL 34926/0015	BOTULINUM TOXIN TYPE A 300 UNITS POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 34926/0015-0091	PL 34926/0015-0091	28/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE EU RISK MANAGEMENT PLANT (RMP) FOR DYSPORT AND BOTULINUM TOXIN TYPE A-HAEMAGGLUTININ CONPLEX FROM VERSION 7.0, DATED

										27 MARCH 2019 TO VERSION 7.2, DATED 19 FEBRUARY 2020.
PL 04854/0136	LEVONORGESTREL 1.5 MG TABLET	GRANTED	PL 04854/0136-0017	PL 04854/0136-0017	29/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO REGISTER AN UPDATED RMP (FROM VERSION 1.2 TO VERSION 1.3).
PL 04416/1346	MATORIDE XL 18 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 04416/1346-0027	PL 04416/1346-0027	31/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE IB - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP TO ALIGN THE RMP CONTENT TO THE RECENT UPDATE OF REFERENCE PRODUCT RITALIN; SUMMARY OF SAFETY CONCERNS HAS BEEN UPDATED ALONG WITH KEY SAFETY MESSAGES IN THE EDUCATIONAL MATERIAL (EM). ADDITIONALLY, THE RMP HAS BEEN TRANSFERRED TO THE NEW RMP TEMPLATE PER ¿GUIDANCE ON THE FORMAT OF THE RISK MANAGEMENT PLAN (RMP) IN THE EU IN INTEGRATED FORMAT (EMA/PRAC/613102/2015 REV.2).
PL 04416/1348	MATORIDE XL 36 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 04416/1348-0027	PL 04416/1348-0027	31/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE IB - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO ALIGN THE RMP CONTENT TO THE RECENT UPDATE OF

								WORKSHARING		REFERENCE PRODUCT RITALIN; SUMMARY OF SAFETY CONCERNS HAS BEEN UPDATED ALONG WITH KEY SAFETY MESSAGES IN THE EDUCATIONAL MATERIAL (EM). ADDITIONALLY, THE RMP HAS BEEN TRANSFERRED TO THE NEW RMP TEMPLATE PER ¿GUIDANCE ON THE FORMAT OF THE RISK MANAGEMENT PLAN (RMP) IN THE EU IN INTEGRATED FORMAT (EMA/PRAC/613102/2015 REV.2).
PL 04416/1349	MATORIDE XL 54 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 04416/1349-0028	PL 04416/1349-0028	31/10/2020	VARIATION	TYPE II	VARV MEDICAL TYPE IB - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RMP TO ALIGN THE RMP CONTENT TO THE RECENT UPDATE OF REFERENCE PRODUCT RITALIN; SUMMARY OF SAFETY CONCERNS HAS BEEN UPDATED ALONG WITH KEY SAFETY MESSAGES IN THE EDUCATIONAL MATERIAL (EM). ADDITIONALLY, THE RMP HAS BEEN TRANSFERRED TO

										THE NEW RMP TEMPLATE PER ¿GUIDANCE ON THE FORMAT OF THE RISK MANAGEMENT PLAN (RMP) IN THE EU IN INTEGRATED FORMAT (EMA/PRAC/613102/2015 REV.2).
PL 08081/0050	ELVANSE 30MG CAPSULES, HARD	GRANTED	PL 08081/0050-0046	PL 08081/0050-0046	01/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SPC IN LINE WITH PRAC AND CMDH RECOMMENDATIONS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 08081/0051	ELVANSE 50 MG CAPSULES, HARD	GRANTED	PL 08081/0051-0047	PL 08081/0051-0047	01/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SPC IN LINE WITH PRAC AND CMDH RECOMMENDATIONS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 08081/0052	ELVANSE 70 MG CAPSULES, HARD	GRANTED	PL 08081/0052-0047	PL 08081/0052-0047	01/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SPC IN LINE WITH PRAC AND CMDH RECOMMENDATIONS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 08081/0062	ELVANSE 20 MG CAPSULES, HARD	GRANTED	PL 08081/0062-0026	PL 08081/0062-0026	01/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SPC IN LINE WITH PRAC AND CMDH RECOMMENDATIONS. CONSEQUENTIALLY,

										THE PIL HAS BEEN UPDATED.
PL 08081/0063	ELVANSE 40 MG CAPSULES, HARD	GRANTED	PL 08081/0063-0026	PL 08081/0063-0026	01/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SPC IN LINE WITH PRAC AND CMDH RECOMMENDATIONS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 08081/0064	ELVANSE 60 MG CAPSULES, HARD	GRANTED	PL 08081/0064-0026	PL 08081/0064-0026	01/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SPC IN LINE WITH PRAC AND CMDH RECOMMENDATIONS. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 00003/0272	LAMICTAL TABLETS 25MG	GRANTED	PL 00003/0272-0141	PL 00003/0272-0141	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC BY ADDING TUBULOINTERSTITIAL NEPHRITIS (TIN) AS A NEW ADVERSE REACTION (UNDESIRABLE EFFECTS) AND THE INVOLVEMENT OF THE KIDNEY IN DRESS (SPECIAL WARNINGS AND PRECAUTIONS FOR USE). CONSEQUENTLY, THE PIL HAS BEEN UPDATED. TABLETS¿ ONLY: SMPC SECTION 2

										UPDATED TO INCLUDE REFERENCE TO ¿LACTOSE¿ AS AN EXCIPIENT OF KNOWN EFFECT.
PL 00003/0273	LAMICTAL TABLETS 50MG	GRANTED	PL 00003/0273-0138	PL 00003/0273-0138	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC BY ADDING TUBULOINTERSTITIAL NEPHRITIS (TIN) AS A NEW ADVERSE REACTION (UNDESIRABLE EFFECTS) AND THE INVOLVEMENT OF THE KIDNEY IN DRESS (SPECIAL WARNINGS AND PRECAUTIONS FOR USE). CONSEQUENTLY, THE PIL HAS BEEN UPDATED. TABLETS¿ ONLY: SMPC SECTION 2 UPDATED TO INCLUDE REFERENCE TO ¿LACTOSE¿ AS AN EXCIPIENT OF KNOWN EFFECT.
PL 00003/0274	LAMICTAL TABLETS 100MG	GRANTED	PL 00003/0274-0132	PL 00003/0274-0132	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC BY ADDING TUBULOINTERSTITIAL NEPHRITIS (TIN) AS A NEW ADVERSE REACTION (UNDESIRABLE EFFECTS) AND THE

										INVOLVEMENT OF THE KIDNEY IN DRESS (SPECIAL WARNINGS AND PRECAUTIONS FOR USE). CONSEQUENTLY, THE PIL HAS BEEN UPDATED. TABLETS¿ ONLY: SMPC SECTION 2 UPDATED TO INCLUDE REFERENCE TO ¿LACTOSE¿ AS AN EXCIPIENT OF KNOWN EFFECT.
PL 00003/0297	LAMICTAL TABLETS 200MG	GRANTED	PL 00003/0297-0138	PL 00003/0297-0138	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC BY ADDING TUBULOINTERSTITIAL NEPHRITIS (TIN) AS A NEW ADVERSE REACTION (UNDESIRABLE EFFECTS) AND THE INVOLVEMENT OF THE KIDNEY IN DRESS (SPECIAL WARNINGS AND PRECAUTIONS FOR USE). CONSEQUENTLY, THE PIL HAS BEEN UPDATED. TABLETS¿ ONLY: SMPC SECTION 2 UPDATED TO INCLUDE REFERENCE TO ¿LACTOSE¿ AS AN

										EXCIPIENT OF KNOWN EFFECT.
PL 00003/0346	LAMICTAL 5 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0346-0150	PL 00003/0346-0150	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC BY ADDING TUBULOINTERSTITIAL NEPHRITIS (TIN) AS A NEW ADVERSE REACTION (UNDESIRABLE EFFECTS) AND THE INVOLVEMENT OF THE KIDNEY IN DRESS (SPECIAL WARNINGS AND PRECAUTIONS FOR USE). CONSEQUENTLY, THE PIL HAS BEEN UPDATED. TABLETS¿ ONLY: SMPC SECTION 2 UPDATED TO INCLUDE REFERENCE TO ¿LACTOSE¿ AS AN EXCIPIENT OF KNOWN EFFECT.
PL 00003/0347	LAMICTAL 25 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0347-0147	PL 00003/0347-0147	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC BY ADDING TUBULOINTERSTITIAL NEPHRITIS (TIN) AS A NEW ADVERSE REACTION (UNDESIRABLE EFFECTS) AND THE INVOLVEMENT OF THE KIDNEY IN DRESS

										(SPECIAL WARNINGS AND PRECAUTIONS FOR USE). CONSEQUENTLY, THE PIL HAS BEEN UPDATED. TABLETS¿ ONLY: SMPC SECTION 2 UPDATED TO INCLUDE REFERENCE TO ¿LACTOSE¿ AS AN EXCIPIENT OF KNOWN EFFECT.
PL 00003/0348	LAMICTAL 100 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0348-0149	PL 00003/0348-0149	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC BY ADDING TUBULOINTERSTITIAL NEPHRITIS (TIN) AS A NEW ADVERSE REACTION (UNDESIRABLE EFFECTS) AND THE INVOLVEMENT OF THE KIDNEY IN DRESS (SPECIAL WARNINGS AND PRECAUTIONS FOR USE). CONSEQUENTLY, THE PIL HAS BEEN UPDATED. TABLETS¿ ONLY: SMPC SECTION 2 UPDATED TO INCLUDE REFERENCE TO ¿LACTOSE¿ AS AN EXCIPIENT OF KNOWN EFFECT.

PL 00003/0368	LAMICTAL 50 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0368-0141	PL 00003/0368-0141	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC BY ADDING TUBULOINTERSTITIAL NEPHRITIS (TIN) AS A NEW ADVERSE REACTION (UNDESIRABLE EFFECTS) AND THE INVOLVEMENT OF THE KIDNEY IN DRESS (SPECIAL WARNINGS AND PRECAUTIONS FOR USE). CONSEQUENTLY, THE PIL HAS BEEN UPDATED. TABLETS¿ ONLY: SMPC SECTION 2 UPDATED TO INCLUDE REFERENCE TO ¿LACTOSE¿ AS AN EXCIPIENT OF KNOWN EFFECT.
PL 00003/0369	LAMICTAL 200 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0369-0139	PL 00003/0369-0139	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC BY ADDING TUBULOINTERSTITIAL NEPHRITIS (TIN) AS A NEW ADVERSE REACTION (UNDESIRABLE EFFECTS) AND THE INVOLVEMENT OF THE KIDNEY IN DRESS (SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

										CONSEQUENTLY, THE PIL HAS BEEN UPDATED. TABLETS¿ ONLY: SMPC SECTION 2 UPDATED TO INCLUDE REFERENCE TO ¿LACTOSE¿ AS AN EXCIPIENT OF KNOWN EFFECT.
PL 00003/0375	LAMICTAL 2MG CHEWABLE/ DISPERSIBLE/ TABLETS	GRANTED	PL 00003/0375-0118	PL 00003/0375-0118	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC BY ADDING TUBULOINTERSTITIAL NEPHRITIS (TIN) AS A NEW ADVERSE REACTION (UNDESIRABLE EFFECTS) AND THE INVOLVEMENT OF THE KIDNEY IN DRESS (SPECIAL WARNINGS AND PRECAUTIONS FOR USE). CONSEQUENTLY, THE PIL HAS BEEN UPDATED. TABLETS¿ ONLY: SMPC SECTION 2 UPDATED TO INCLUDE REFERENCE TO ¿LACTOSE¿ AS AN EXCIPIENT OF KNOWN EFFECT.
PL 36390/0218	TADALAFIL 2.5 MG FILM-COATED TABLETS	GRANTED	PL 36390/0	PL 36390/0	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	INTRODUCTION OF, OR CHANGE(S) TO, THE OBLIGATIONS

			218-0007	218-0007				(STANDARD) - CMS		AND CONDITIONS OF A MARKETING AUTHORISATION, INCLUDING THE RISK MANAGEMENT PLAN.
PL 36390/0219	TADALAFIL 5 MG FILM-COATED TABLETS	GRANTED	PL 36390/0219-0007	PL 36390/0219-0007	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	INTRODUCTION OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING AUTHORISATION, INCLUDING THE RISK MANAGEMENT PLAN.
PL 36390/0220	TADALAFIL 10 MG FILM-COATED TABLETS	GRANTED	PL 36390/0220-0006	PL 36390/0220-0006	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	INTRODUCTION OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING AUTHORISATION, INCLUDING THE RISK MANAGEMENT PLAN.
PL 36390/0221	TADALAFIL 20 MG FILM-COATED TABLETS	GRANTED	PL 36390/0221-0006	PL 36390/0221-0006	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	INTRODUCTION OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING AUTHORISATION, INCLUDING THE RISK MANAGEMENT PLAN.
PL 36390/0222	TADALAFIL 20 MG FILM-COATED TABLETS	GRANTED	PL 36390/0222-0006	PL 36390/0222-0006	03/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	INTRODUCTION OF, OR CHANGE(S) TO, THE OBLIGATIONS AND CONDITIONS OF A MARKETING AUTHORISATION, INCLUDING THE RISK MANAGEMENT PLAN WHICH HAS BEEN

										UPDATED TO VERSION 1.2.
PL 00242/0301	TOPAMAX 25 MG FILM-COATED TABLETS	GRANTED	PL 00242/0301-0154	PL 00242/0301-0154	05/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SPC TO REGISTER THE ADDITION OF WARNING TEXT REGARDING STEVENS-JOHNSON SYNDROME AND TOXIC EPIDERMAL NECROLYSIS. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED. TO REGISTER THE REMOVAL OF THE SODIUM INFORMATION IN SECTION 4.4 OF THE SMPC AND SECTION 2 OF THE PL IN ALIGNMENT WITH THE ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE.

										ADDITIONALLY, TO UPDATE SECTION 5.1 FOR ALIGNMENT OF THE DESCRIPTION OF THE PHARMACOTHERAPEUTIC GROUP WITH THE CURRENT WHO ATC CLASSIFICATION.
PL 00242/0302	TOPAMAX 50 MG FILM-COATED TABLETS	GRANTED	PL 00242/0302-0155	PL 00242/0302-0155	05/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - NATIONAL	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SPC TO REGISTER THE ADDITION OF WARNING TEXT REGARDING STEVENS-JOHNSON SYNDROME AND TOXIC EPIDERMAL NECROLYSIS. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED. TO REGISTER THE REMOVAL OF THE SODIUM INFORMATION IN SECTION 4.4 OF THE SMPC AND SECTION 2 OF THE PL IN ALIGNMENT WITH THE ANNEX TO THE EUROPEAN COMMISSION

										GUIDELINE ON EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE. ADDITIONALLY, TO UPDATE SECTION 5.1 FOR ALIGNMENT OF THE DESCRIPTION OF THE PHARMACOTHERAPEUTIC GROUP WITH THE CURRENT WHO ATC CLASSIFICATION.
PL 00242/0303	TOPAMAX 100 MG FILM-COATED TABLETS	GRANTED	PL 00242/0303-0156	PL 00242/0303-0156	05/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - NATIONAL	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SPC TO REGISTER THE ADDITION OF WARNING TEXT REGARDING STEVENS-JOHNSON SYNDROME AND TOXIC EPIDERMAL NECROLYSIS. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED. TO REGISTER THE REMOVAL OF THE

										SODIUM INFORMATION IN SECTION 4.4 OF THE SMPC AND SECTION 2 OF THE PL IN ALIGNMENT WITH THE ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE. ADDITIONALLY, TO UPDATE SECTION 5.1 FOR ALIGNMENT OF THE DESCRIPTION OF THE PHARMACOTHERAPEUTIC GROUP WITH THE CURRENT WHO ATC CLASSIFICATION.
PL 00242/0304	TOPAMAX 200 MG FILM-COATED TABLETS	GRANTED	PL 00242/0304-0154	PL 00242/0304-0154	05/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - NATIONAL	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SPC TO REGISTER THE ADDITION OF WARNING TEXT REGARDING STEVENS-JOHNSON SYNDROME AND TOXIC EPIDERMAL NECROLYSIS. CONSEQUENTLY, THE PATIENT

										INFORMATION LEAFLET HAS ALSO BEEN UPDATED. TO REGISTER THE REMOVAL OF THE SODIUM INFORMATION IN SECTION 4.4 OF THE SMPC AND SECTION 2 OF THE PL IN ALIGNMENT WITH THE ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE. ADDITIONALLY, TO UPDATE SECTION 5.1 FOR ALIGNMENT OF THE DESCRIPTION OF THE PHARMACOTHERAPEUTIC GROUP WITH THE CURRENT WHO ATC CLASSIFICATION.
PL 00242/0348	TOPAMAX SPRINKLE 15 MG HARD CAPSULES	GRANTED	PL 00242/0348-0132	PL 00242/0348-0132	05/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SPC TO REGISTER THE ADDITION OF

								RD) - NATIONAL		WARNING TEXT REGARDING STEVENS-JOHNSON SYNDROME AND TOXIC EPIDERMAL NECROLYSIS. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED. TO REGISTER THE REMOVAL OF THE SODIUM INFORMATION IN SECTION 4.4 OF THE SMPC AND SECTION 2 OF THE PL IN ALIGNMENT WITH THE ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE. ADDITIONALLY, TO UPDATE SECTION 5.1 FOR ALIGNMENT OF THE DESCRIPTION OF THE

										PHARMACOTHERAPEUTIC GROUP WITH THE CURRENT WHO ATC CLASSIFICATION.
PL 00242/0349	TOPAMAX SPRINKLE 25 MG HARD CAPSULES	GRANTED	PL 00242/0349-0134	PL 00242/0349-0134	05/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - NATIONAL	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SPC TO REGISTER THE ADDITION OF WARNING TEXT REGARDING STEVENS-JOHNSON SYNDROME AND TOXIC EPIDERMAL NECROLYSIS. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED. TO REGISTER THE REMOVAL OF THE SODIUM INFORMATION IN SECTION 4.4 OF THE SMPC AND SECTION 2 OF THE PL IN ALIGNMENT WITH THE ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE.

										ADDITIONALLY, TO UPDATE SECTION 5.1 FOR ALIGNMENT OF THE DESCRIPTION OF THE PHARMACOTHERAPEUTIC GROUP WITH THE CURRENT WHO ATC CLASSIFICATION.
PL 00242/0350	TOPAMAX SPRINKLE 50 MG HARD CAPSULES	GRANTED	PL 00242/0350-0132	PL 00242/0350-0132	05/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - NATIONAL	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SPC TO REGISTER THE ADDITION OF WARNING TEXT REGARDING STEVENS-JOHNSON SYNDROME AND TOXIC EPIDERMAL NECROLYSIS. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED. TO REGISTER THE REMOVAL OF THE SODIUM INFORMATION IN SECTION 4.4 OF THE SMPC AND SECTION 2 OF THE PL IN ALIGNMENT WITH THE ANNEX TO THE EUROPEAN

										COMMISSION GUIDELINE ON EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE. ADDITIONALLY, TO UPDATE SECTION 5.1 FOR ALIGNMENT OF THE DESCRIPTION OF THE PHARMACOTHERAPEUTIC GROUP WITH THE CURRENT WHO ATC CLASSIFICATION.
PL 21344/0023	ANAGRELIDE AOP 0.5 MG HARD CAPSULES	GRANTED	PL 21344/0023-0005	PL 21344/0023-0005	08/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE RMP (VERSION 2.0) FOR ALL EU NATIONAL LICENSES (THROMBOREDUCTIN) AND LICENSES REGISTERED VIA DCP (AT/H/0722/001/DC, ANAGRELIDE AOP) IN EU UPON THE NEW PHARMACOVIGILANCE DATA GATHERED WITHIN LAST PSUSA PROCEDURES (EMEA/H/C/PSUSA/00000208/201709, EMEA/H/C/PSUSA/00000208/201809) AND OTHER EDITORIAL

										CHANGES (FORMAL CHANGES, REFORMULATIONS AND NEW FORMAT OF RMP).
PL 21344/0023	ANAGRELIDE AOP 0.5 MG HARD CAPSULES	GRANTED	PL 21344/0023-0006	PL 21344/0023-0006	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC DUE TO OCCURRED SIGNAL FOR ADVERSE EVENT - HYPOAESTHESIA BASED ON PSUR #15 (COVERING PERIOD 14.09.2018-13.09.2019) SUBMITTED WITHIN PROCEDURE PSUSA/00000208/201909.
PL 00031/0160	ROACCUTANE 20 MG SOFT CAPSULES	GRANTED	PL 00031/0160-0165	PL 00031/0160-0165	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 00031/0617	ROACCUTANE 10MG SOFT CAPSULES	GRANTED	PL 00031/0617-0111	PL 00031/0617-0111	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY

										PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 04569/1343	ISOTRETINOIN 5 MG SOFT CAPSULES	GRANTED	PL 04569/1343-0044	PL 04569/1343-0044	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 04569/1343	ISOTRETINOIN MYLAN 5 MG CAPSULES	GRANTED	PL 04569/1343-0044	PL 04569/1343-0044	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 04569/1344	ISOTRETINOIN 10 MG SOFT CAPSULES	GRANTED	PL 04569/1344-0045	PL 04569/1344-0045	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY

										PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 04569/1344	ISOTRETINOIN MYLAN 10 MG CAPSULES	GRANTED	PL 04569/1344-0045	PL 04569/1344-0045	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 04569/1345	ISOTRETINOIN 20 MG SOFT CAPSULES	GRANTED	PL 04569/1345-0045	PL 04569/1345-0045	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 04569/1345	ISOTRETINOIN MYLAN 20 MG CAPSULES	GRANTED	PL 04569/1345-0045	PL 04569/1345-0045	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY

										PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 04569/1346	ISOTRETINOIN 40 MG SOFT CAPSULES	GRANTED	PL 04569/1346-0044	PL 04569/1346-0044	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 04569/1346	ISOTRETINOIN MYLAN 40 MG CAPSULES	GRANTED	PL 04569/1346-0044	PL 04569/1346-0044	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 06831/0251	ACITRETIN 10 MG CAPSULES	GRANTED	PL 06831/0251-0030	PL 06831/0251-0030	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY

										PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 06831/0252	ACITRETIN 25 MG CAPSULES	GRANTED	PL 06831/0252-0029	PL 06831/0252-0029	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 16853/0132	ISOTRETINOIN 5MG CAPSULES	GRANTED	PL 16853/0132-0029	PL 16853/0132-0029	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 16853/0132	RIZUDERM 5 MG CAPSULES	GRANTED	PL 16853/0132-0029	PL 16853/0132-0029	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY

										PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 16853/0133	ISOTRETINOIN 20MG CAPSULES	GRANTED	PL 16853/0133-0031	PL 16853/0133-0031	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 16853/0133	RIZUDERM 20 MG CAPSULES	GRANTED	PL 16853/0133-0031	PL 16853/0133-0031	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 19494/0252	TOCTINO 10MG SOFT CAPSULES	GRANTED	PL 19494/0252-0030	PL 19494/0252-0030	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY

										PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 19494/0253	TOCTINO 30MG SOFT CAPSULES	GRANTED	PL 19494/0253-0030	PL 19494/0253-0030	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 30306/0096	ACITRETIN 10MG CAPSULES	GRANTED	PL 30306/0096-0064	PL 30306/0096-0064	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 30306/0096	NEOTIGASON CAPSULES 10MG	GRANTED	PL 30306/0096-0064	PL 30306/0096-0064	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY

										PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 30306/0097	ACITRETIN 25MG CAPSULES	GRANTED	PL 30306/0097-0059	PL 30306/0097-0059	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 30306/0097	NEOTIGASON CAPSULES 25MG	GRANTED	PL 30306/0097-0059	PL 30306/0097-0059	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 31750/0099	ISOTRETINOIN 10 MG SOFT CAPSULES	GRANTED	PL 31750/0099-0011	PL 31750/0099-0011	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY

										PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 31750/0100	ISOTRETINOIN 20 MG SOFT CAPSULES	GRANTED	PL 31750/0100-0011	PL 31750/0100-0011	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 40739/0001	ISOTRETINOIN 20MG SOFT CAPSULES	GRANTED	PL 40739/0001-0040	PL 40739/0001-0040	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 40739/0001	RETICUTAN 20MG SOFT CAPSULES.	GRANTED	PL 40739/0001-0040	PL 40739/0001-0040	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY

										PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 40739/0002	ISOTRETINOIN 5 MG CAPSULES	GRANTED	PL 40739/0002-0021	PL 40739/0002-0021	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 40739/0041	ISOTRETINOIN 10 MG CAPSULES, SOFT	GRANTED	PL 40739/0041-0008	PL 40739/0041-0008	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 40739/0216	ALITRETINOIN 10 MG CAPSULES	GRANTED	PL 40739/0216-0005	PL 40739/0216-0005	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY

										PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 40739/0217	ALITRETINOIN 30 MG CAPSULES	GRANTED	PL 40739/0217-0005	PL 40739/0217-0005	09/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO REQUEST A REVIEW OF A SURVEY STUDY PROTOCOL (CATEGORY 3 STUDY) TO ASSESS THE EFFECTIVENESS OF PREGNANCY PREVENTION PROGRAMME (PPP) FOR ORAL MEDICINES CONTAINING RETINOIDS.
PL 08081/0040	MEZAVANT XL 1200MG, GASTRO-RESISTANT, PROLONGED RELEASE TABLETS	GRANTED	PL 08081/0040-0042	PL 08081/0040-0042	12/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SMPC AND PIL WITH THE RECENT UPDATES TO SHIRE'S COMPANY CORE DATA SHEET (CCDS) VERSION -22
PL 14776/0092	ACTIQ 200 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0092-0046	PL 14776/0092-0046	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION,

										ADDITIONAL INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0092	ACTIQ 200 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0092-0046	PL 14776/0092-0046	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION

										WITH ADRENAL INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0093	ACTIQ 400 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0093-0048	PL 14776/0093-0048	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0093	ACTIQ 400 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL	GRANTED	PL 14776/0093-0048	PL 14776/0093-0048	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME -

	OROMUCOSAL APPLICATOR							RD) - CMS		OUTCOME OF PSUSA PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0094	ACTIQ 600 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0094-0048	PL 14776/0094-0048	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL

										INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0094	ACTIQ 600 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0094-0048	PL 14776/0094-0048	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL

										INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0095	ACTIQ 800 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0095-0050	PL 14776/0095-0050	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0095	ACTIQ 800 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL	GRANTED	PL 14776/0095-0050	PL 14776/0095-0050	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA

	OROMUCOSAL APPLICATOR									PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0096	ACTIQ 1,200 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0096-0047	PL 14776/0096-0047	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL INFORMATION IN

										SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0096	ACTIQ 1,200 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0096-0047	PL 14776/0096-0047	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL INSUFFICIENCY AND

										ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0097	ACTIQ 1,600 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0097-0048	PL 14776/0097-0048	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA PROCEDURE EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 14776/0097	ACTIQ 1,600 MICROGRAMS COMPRESSED LOZENGE WITH INTEGRAL OROMUCOSAL APPLICATOR	GRANTED	PL 14776/0097-0048	PL 14776/0097-0048	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 6.1 OF THE SMPC AND PIL TO IMPLEMENT OUTCOME OF PSUR OUTCOME - OUTCOME OF PSUSA PROCEDURE

										EMEA/H/C/PSUSA/00001369/201704 CONCLUDED IN VIEW OF THE POTENTIAL BIOLOGICAL PLAUSIBILITY FOR ASSOCIATION, ADDITIONAL INFORMATION IN SECTION 5.1 OF THE SMPC ON THE POTENTIAL EFFECT OF FENTANYL ON HYPOTHALAMIC-PITUITARY-ADRENAL AND GONADAL AXIS AND ITS CONNECTION WITH ADRENAL INSUFFICIENCY AND ANDROGEN DEFICIENCY IS WARRANTED.
PL 41042/0001	DUODOPA 20MG/ML + 5MG/ML, INTESTINAL GEL	GRANTED	PL 41042/0001-0045	PL 41042/0001-0045	17/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.8 AND 5.1 OF THE SMPC AND PIL IN LINE WITH THE UPDATED COMPANY CORE DATA SHEET. ADDITIONALLY EDITORIAL CHANGES HAS BEEN MADE TO THE PRODUCT INFORMATION IN LINE WITH THE FINAL ENGLISH SMPC.
PL 04416/0913	CITALOPRAM 10MG TABLETS	GRANTED	PL 04416/0913-0045	PL 04416/0913-0045	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.2, 5.3, 6.3, 6.5 AND 6.6 OF

								RD) - CMS		THE SMPC IN LINE WITH THE NOT HARMONISED REFERENCE PRODUCT, CIPRAMIL 10 MG FILMDRAGERADE TABLETTER (MAH: H. LUNDBECK A/S - DATED AUGUST 2019). CONSEQUENTLY, THE PACKAGE LABELLING AND PIL HAVE BEEN UPDATED.
PL 11648/0071	CARDICOR 1.25MG FILM-COATED TABLETS	GRANTED	PL 11648/0071-0043	PL 11648/0071-0043	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND SECTION 4 OF PIL TO ADD ADVERSE REACTION ANGIODEMA TO THE RELEVANT SECTION OF PRODUCT INFORMATION, FOLLOWING A SIGNAL EVALUATION TRIGGERED BY MHRA REQUEST.
PL 11648/0072	CARDICOR 2.5MG FILM-COATED TABLETS	GRANTED	PL 11648/0072-0044	PL 11648/0072-0044	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND SECTION 4 OF PIL TO ADD ADVERSE REACTION ANGIODEMA TO THE RELEVANT SECTION OF PRODUCT INFORMATION, FOLLOWING A SIGNAL EVALUATION

										TRIGGERED BY MHRA REQUEST.
PL 11648/0073	CARDICOR 3.75MG FILM-COATED TABLETS	GRANTED	PL 11648/0073-0043	PL 11648/0073-0043	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND SECTION 4 OF PIL TO ADD ADVERSE REACTION ANGIODEMA TO THE RELEVANT SECTION OF PRODUCT INFORMATION, FOLLOWING A SIGNAL EVALUATION TRIGGERED BY MHRA REQUEST.
PL 11648/0074	CARDICOR 5.0MG FILM-COATED TABLETS	GRANTED	PL 11648/0074-0043	PL 11648/0074-0043	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND SECTION 4 OF PIL TO ADD ADVERSE REACTION ANGIODEMA TO THE RELEVANT SECTION OF PRODUCT INFORMATION, FOLLOWING A SIGNAL EVALUATION TRIGGERED BY MHRA REQUEST.
PL 11648/0075	CARDICOR 7.5MG FILM-COATED TABLETS	GRANTED	PL 11648/0075-0043	PL 11648/0075-0043	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND SECTION 4 OF PIL TO ADD ADVERSE REACTION ANGIODEMA TO THE RELEVANT SECTION OF PRODUCT INFORMATION, FOLLOWING A SIGNAL

										EVALUATION TRIGGERED BY MHRA REQUEST.
PL 11648/0076	CARDICOR 10.0MG FILM-COATED TABLETS	GRANTED	PL 11648/0076-0044	PL 11648/0076-0044	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND SECTION 4 OF PIL TO ADD ADVERSE REACTION ANGIODEMA TO THE RELEVANT SECTION OF PRODUCT INFORMATION, FOLLOWING A SIGNAL EVALUATION TRIGGERED BY MHRA REQUEST.
PL 34926/0001	DYSPORT 500 UNITS POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 34926/0001-0099	PL 34926/0001-0099	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO ADD A NEW ADVERSE DRUG REACTION ¿HYPOAESTHESIA¿ WITH A FREQUENCY "UNKNOWN" TO SECTION 4.8 "UNDESIRABLE EFFECTS" OF THE SUMMARY OF PRODUCT CHARACTERISTICS (SMPC), AND CORRESPONDING UPDATE IN THE PATIENT INFORMATION LEAFLET (PIL). IN ORDER TO SUPPORT THE

										HEALTHCARE PRODUCTS SUPPLY CHAIN AND WIDER RESPONSE TO THE COVID-19 OUTBREAK, TEXT VERSIONS OF THE PIL/LABELLING HAVE BEEN ACCEPTED
PL 34926/0009	BOTULINUM TOXIN TYPE A 500 UNITS POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 34926/0009-0095	PL 34926/0009-0095	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO ADD A NEW ADVERSE DRUG REACTION ¿HYPOAESTHESIA¿ WITH A FREQUENCY "UNKNOWN" TO SECTION 4.8 "UNDESIRABLE EFFECTS" OF THE SUMMARY OF PRODUCT CHARACTERISTICS (SMPC), AND CORRESPONDING UPDATE IN THE PATIENT INFORMATION LEAFLET (PIL). IN ORDER TO SUPPORT THE HEALTHCARE PRODUCTS SUPPLY CHAIN AND WIDER RESPONSE TO THE COVID-19 OUTBREAK, TEXT VERSIONS OF THE PIL/LABELLING

										HAVE BEEN ACCEPTED
PL 34926/0014	DYSPORT 300 UNITS POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 34926/0014-0084	PL 34926/0014-0084	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO ADD A NEW ADVERSE DRUG REACTION ¿HYPOAESTHESIA¿ WITH A FREQUENCY "UNKNOWN" TO SECTION 4.8 "UNDESIRABLE EFFECTS" OF THE SUMMARY OF PRODUCT CHARACTERISTICS (SMPC), AND CORRESPONDING UPDATE IN THE PATIENT INFORMATION LEAFLET (PIL). IN ORDER TO SUPPORT THE HEALTHCARE PRODUCTS SUPPLY CHAIN AND WIDER RESPONSE TO THE COVID-19 OUTBREAK, TEXT VERSIONS OF THE PIL/LABELLING HAVE BEEN ACCEPTED
PL 34926/0015	BOTULINUM TOXIN TYPE A 300 UNITS POWDER FOR	GRANTED	PL 34926/0015-0089	PL 34926/0015-0089	19/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO ADD A NEW ADVERSE DRUG REACTION ¿HYPOAESTHESIA¿

	SOLUTION FOR INJECTION							(COMPLEX) - CMS		WITH A FREQUENCY "UNKNOWN" TO SECTION 4.8 "UNDESIRABLE EFFECTS" OF THE SUMMARY OF PRODUCT CHARACTERISTICS (SMPC), AND CORRESPONDING UPDATE IN THE PATIENT INFORMATION LEAFLET (PIL). IN ORDER TO SUPPORT THE HEALTHCARE PRODUCTS SUPPLY CHAIN AND WIDER RESPONSE TO THE COVID-19 OUTBREAK, TEXT VERSIONS OF THE PIL/LABELLING HAVE BEEN ACCEPTED
PL 06831/0273	AMOROLFINE HYDROCHLORIDE 5% W/V NAIL LACQUER	GRANTED	PL 06831/0273-0023	PL 06831/0273-0023	20/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.1-4.9, 5.1, 5.3, 6.3, 6.4 AND 6.5 OF THE SMPC AND PIL PRODUCT NOT MARKETED.

PL 00057/0626	CAMPTO 40MG/2ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00057/0626-0060	PL 00057/0626-0060	23/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL IN LINE WITH EU EXCIPIENT GUIDELINES (OCT. 2017).
PL 00057/0627	CAMPTO 20MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00057/0627-0065	PL 00057/0627-0065	23/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL IN LINE WITH EU EXCIPIENT GUIDELINES (OCT. 2017).
PL 50622/0046	NEURONTIN 100MG HARD CAPSULES	GRANTED	PL 50622/0046-0006	PL 50622/0046-0006	27/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO PROVIDE A STUDY PROTOCOL (STUDY A9451182) FOR A POPULATION-BASED COHORT STUDY OF GABAPENTIN TO CHARACTERIZE PREGNANCY OUTCOMES IN RESPONSE TO QUESTION 2 AND 3 FOLLOWING THE MOST RECENT 2019 PERIODIC SAFETY UPDATE REPORT (PSUR) - PSUSA/00001499/201902 COVERING PERIOD 02 FEBRUARY 2016 TO 01 FEBRUARY 2019 PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE (PRAC) ISSUED THE

										ASSESSMENT REPORT (AR).
PL 50622/0047	NEURONTIN 300MG HARD CAPSULES	GRANTED	PL 50622/0047-0006	PL 50622/0047-0006	27/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO PROVIDE A STUDY PROTOCOL (STUDY A9451182) FOR A POPULATION-BASED COHORT STUDY OF GABAPENTIN TO CHARACTERIZE PREGNANCY OUTCOMES IN RESPONSE TO QUESTION 2 AND 3 FOLLOWING THE MOST RECENT 2019 PERIODIC SAFETY UPDATE REPORT (PSUR) - PSUSA/00001499/201902 COVERING PERIOD 02 FEBRUARY 2016 TO 01 FEBRUARY 2019 PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE (PRAC) ISSUED THE ASSESSMENT REPORT (AR).
PL 50622/0048	NEURONTIN 400MG HARD CAPSULES	GRANTED	PL 50622/0048-0006	PL 50622/0048-0006	27/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO PROVIDE A STUDY PROTOCOL (STUDY A9451182) FOR A POPULATION-BASED COHORT STUDY OF GABAPENTIN TO

										CHARACTERIZE PREGNANCY OUTCOMES IN RESPONSE TO QUESTION 2 AND 3 FOLLOWING THE MOST RECENT 2019 PERIODIC SAFETY UPDATE REPORT (PSUR) - PSUSA/00001499/201902 COVERING PERIOD 02 FEBRUARY 2016 TO 01 FEBRUARY 2019 PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE (PRAC) ISSUED THE ASSESSMENT REPORT (AR).
PL 50622/0049	NEURONTIN 600MG FILM-COATED TABLETS	GRANTED	PL 50622/0049-0006	PL 50622/0049-0006	27/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO PROVIDE A STUDY PROTOCOL (STUDY A9451182) FOR A POPULATION-BASED COHORT STUDY OF GABAPENTIN TO CHARACTERIZE PREGNANCY OUTCOMES IN RESPONSE TO QUESTION 2 AND 3 FOLLOWING THE MOST RECENT 2019 PERIODIC SAFETY UPDATE REPORT (PSUR) - PSUSA/00001499/20190

										2 COVERING PERIOD 02 FEBRUARY 2016 TO 01 FEBRUARY 2019 PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE (PRAC) ISSUED THE ASSESSMENT REPORT (AR).
PL 50622/0050	NEURONTIN 800MG FILM-COATED TABLETS	GRANTED	PL 50622/0050-0006	PL 50622/0050-0006	27/11/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO PROVIDE A STUDY PROTOCOL (STUDY A9451182) FOR A POPULATION-BASED COHORT STUDY OF GABAPENTIN TO CHARACTERIZE PREGNANCY OUTCOMES IN RESPONSE TO QUESTION 2 AND 3 FOLLOWING THE MOST RECENT 2019 PERIODIC SAFETY UPDATE REPORT (PSUR) - PSUSA/00001499/201902 COVERING PERIOD 02 FEBRUARY 2016 TO 01 FEBRUARY 2019 PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE (PRAC) ISSUED THE ASSESSMENT REPORT (AR).

PL 04416/0807	VINORELBINE 10 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 04416/0807-0038	PL 04416/0807-0038	01/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.3, 4.4, 4.6, 4.7, 4.8, 4.9, 5.1, 6.3, 6.4, 6.5, 9 AND 10 OF THE SPC TO THE NOT HARMONISED REFERENCE PRODUCT NAVELBINE, 10 MG INFUSIONSKONZENTRAT, PIERRE FABRE MEDICAMENT, DATED DECEMBER 2015. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 00101/0212	OCTREOTIDE AMPOULES 50 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00101/0212-0133	PL 00101/0212-0133	03/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC AND PIL TO ADD `CHOLANGITIS' AS A COMPLICATION OF CHOLELITHIASIS UNDER THE SUBSECTION `GALLBLADDER-RELATED EVENTS', AS WELL AS THE PACKAGE LEAFLET SECTION 2 `WARNINGS AND PRECAUTIONS'. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC AND PIL.
PL 00101/0212	SANDOSTATIN AMPOULES 50 MCG/ML SOLUTION FOR INJECTION OR	GRANTED	PL 00101/0212-0133	PL 00101/0212-0133	03/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC AND PIL TO ADD `CHOLANGITIS' AS A

	CONCENTRATE FOR SOLUTION FOR INFUSION							RD) - CMS		COMPLICATION OF CHOLELITHIASIS UNDER THE SUBSECTION `GALLBLADDER-RELATED EVENTS', AS WELL AS THE PACKAGE LEAFLET SECTION 2 `WARNINGS AND PRECAUTIONS'. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC AND PIL.
PL 00101/0213	OCTREOTIDE AMPOULES 100 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00101/0213-0131	PL 00101/0213-0131	03/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC AND PIL TO ADD `CHOLANGITIS' AS A COMPLICATION OF CHOLELITHIASIS UNDER THE SUBSECTION `GALLBLADDER-RELATED EVENTS', AS WELL AS THE PACKAGE LEAFLET SECTION 2 `WARNINGS AND PRECAUTIONS'. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC AND PIL.
PL 00101/0213	SANDOSTATIN AMPOULES 100 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR	GRANTED	PL 00101/0213-0131	PL 00101/0213-0131	03/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC AND PIL TO ADD `CHOLANGITIS' AS A COMPLICATION OF

	SOLUTION FOR INFUSION							RD) - CMS		CHOLELITHIASIS UNDER THE SUBSECTION `GALLBLADDER-RELATED EVENTS', AS WELL AS THE PACKAGE LEAFLET SECTION 2 `WARNINGS AND PRECAUTIONS'. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC AND PIL.
PL 00101/0214	OCTREOTIDE AMPOULES 500 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00101/0214-0129	PL 00101/0214-0129	03/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC AND PIL TO ADD `CHOLANGITIS' AS A COMPLICATION OF CHOLELITHIASIS UNDER THE SUBSECTION `GALLBLADDER-RELATED EVENTS', AS WELL AS THE PACKAGE LEAFLET SECTION 2 `WARNINGS AND PRECAUTIONS'. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC AND PIL.
PL 00101/0214	SANDOSTATIN AMPOULES 500 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR	GRANTED	PL 00101/0214-0129	PL 00101/0214-0129	03/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC AND PIL TO ADD `CHOLANGITIS' AS A COMPLICATION OF CHOLELITHIASIS

	SOLUTION FOR INFUSION									UNDER THE SUBSECTION `GALLBLADDER-RELATED EVENTS', AS WELL AS THE PACKAGE LEAFLET SECTION 2 `WARNINGS AND PRECAUTIONS'. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC AND PIL.
PL 00101/0511	SANDOSTATIN LAR 10 MG POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 00101/0511-0120	PL 00101/0511-0120	03/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC AND PIL TO ADD `CHOLANGITIS' AS A COMPLICATION OF CHOLELITHIASIS UNDER THE SUBSECTION `GALLBLADDER-RELATED EVENTS', AS WELL AS THE PACKAGE LEAFLET SECTION 2 `WARNINGS AND PRECAUTIONS'. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC AND PIL.
PL 00101/0512	SANDOSTATIN LAR 20 MG POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 00101/0512-0117	PL 00101/0512-0117	03/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC AND PIL TO ADD `CHOLANGITIS' AS A COMPLICATION OF CHOLELITHIASIS UNDER THE

										SUBSECTION `GALLBLADDER-RELATED EVENTS', AS WELL AS THE PACKAGE LEAFLET SECTION 2 `WARNINGS AND PRECAUTIONS'. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC AND PIL.
PL 00101/0513	SANDOSTATIN LAR 30 MG POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 00101/0513-0117	PL 00101/0513-0117	03/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC AND PIL TO ADD `CHOLANGITIS' AS A COMPLICATION OF CHOLELITHIASIS UNDER THE SUBSECTION `GALLBLADDER-RELATED EVENTS', AS WELL AS THE PACKAGE LEAFLET SECTION 2 `WARNINGS AND PRECAUTIONS'. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SMPC AND PIL.
PL 39307/0041	DIPYRIDAMOLE 200MG/5ML ORAL SUSPENSION	GRANTED	PL 39307/0041-0013	PL 39307/0041-0013	04/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SMPC AND PIL

PL 04416/1599	EBETREX 20 MG/ML SOLUTION FOR INJECTION, PRE-FILLED SYRINGE	GRANTED	PL 04416/1599-0004	PL 04416/1599-0004	07/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP TO VERSION 4.2, INCLUDING THE DELETION OF EDUCATIONAL MATERIAL WHICH SERVED AS AN ADDITIONAL RISK MINIMISATION MATERIAL (AVOIDING RISKS OF TERATOGENICITY AND CONTAMINATION DURING ADMINISTRATION OR DISPOSAL), IN-LINE WITH THE REFERENCE PRODUCT.
PL 27925/0011	INDIVINA 1MG/2.5MG TABLETS	GRANTED	PL 27925/0011-0041	PL 27925/0011-0041	07/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1-4.9, 5.1 AND 6.6 OF THE SMPC AND PIL IN LINE WITH NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA FOR INDIVINA 1/2.5MG, 1/5MG AND 2/5MG TABLETS.
PL 27925/0012	INDIVINA 1MG/5MG TABLETS	GRANTED	PL 27925/0012-0037	PL 27925/0012-0037	07/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1-4.9, 5.1 AND 6.6 OF THE SMPC AND PIL IN LINE WITH NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA FOR INDIVINA

										1/2.5MG, 1/5MG AND 2/5MG TABLETS.
PL 27925/0013	INDIVINA 2MG/5MG TABLETS	GRANTED	PL 27925/0013-0037	PL 27925/0013-0037	07/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.1-4.9, 5.1 AND 6.6 OF THE SMPC AND PIL IN LINE WITH NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA FOR INDIVINA 1/2.5MG, 1/5MG AND 2/5MG TABLETS.
PL 10590/0015	DIFFERIN 0.1% W/W GEL	GRANTED	PL 10590/0015-0065	PL 10590/0015-0065	09/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE A RISK MANAGEMENT PLAN (RMP) (VERSION 2).
PL 10590/0029	DIFFERIN 0.1% W/W CREAM	GRANTED	PL 10590/0029-0061	PL 10590/0029-0061	09/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE A RISK MANAGEMENT PLAN (RMP) (VERSION 2).
PL 48998/0001	ZEVTERA 500MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 48998/0001-0015	PL 48998/0001-0015	09/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER AN UPDATED RMP (FROM VERSION 5.1 TO VERSION 6.2) AND UPDATE SECTIONS 4.4 & 4.8 OF THE SMPC, AND CORRESPONDING SECTIONS OF THE PIL

PL 16950/0084	ZAMADOL 24HR 150MG PROLONGED RELEASE TABLETS	GRANTED	PL 16950/0084-0083	PL 16950/0084-0083	10/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1)TO UPDATE SECTIONS 4.4, 4.5 OF THE SMPC AND PIL IN LINE WITH THE CMDH/372/2018 RECOMMENDATION OF FEBRUARY 2018 (CONCOMITANT USE OF BENZODIAZEPINES/ BENZODIAZEPINE-LIKE PRODUCTS AND OPIOIDS). 2) TO UPDATE SECTION 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.2 AND 5.3 OF THE SMPC AND PIL IN LINE WITH COMPANY CORE DATA SHEET (CCDS V.16).
PL 16950/0085	ZAMADOL 24HR 200MG PROLONGED RELEASE TABLETS	GRANTED	PL 16950/0085-0080	PL 16950/0085-0080	10/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1)TO UPDATE SECTIONS 4.4, 4.5 OF THE SMPC AND PIL IN LINE WITH THE CMDH/372/2018 RECOMMENDATION OF FEBRUARY 2018 (CONCOMITANT USE OF BENZODIAZEPINES/ BENZODIAZEPINE-LIKE PRODUCTS AND OPIOIDS). 2) TO UPDATE SECTION 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.2 AND 5.3 OF THE SMPC

										AND PIL IN LINE WITH COMPANY CORE DATA SHEET (CCDS V.16).
PL 16950/0086	ZAMADOL 24HR 300MG PROLONGED RELEASE TABLETS	GRANTED	PL 16950/0086-0079	PL 16950/0086-0079	10/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1)TO UPDATE SECTIONS 4.4, 4.5 OF THE SMPC AND PIL IN LINE WITH THE CMDH/372/2018 RECOMMENDATION OF FEBRUARY 2018 (CONCOMITANT USE OF BENZODIAZEPINES/ BENZODIAZEPINE-LIKE PRODUCTS AND OPIOIDS). 2) TO UPDATE SECTION 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.2 AND 5.3 OF THE SMPC AND PIL IN LINE WITH COMPANY CORE DATA SHEET (CCDS V.16).
PL 16950/0087	ZAMADOL 24HR 400MG PROLONGED RELEASE TABLETS	GRANTED	PL 16950/0087-0080	PL 16950/0087-0080	10/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1)TO UPDATE SECTIONS 4.4, 4.5 OF THE SMPC AND PIL IN LINE WITH THE CMDH/372/2018 RECOMMENDATION OF FEBRUARY 2018 (CONCOMITANT USE OF BENZODIAZEPINES/ BENZODIAZEPINE-LIKE PRODUCTS AND OPIOIDS). 2) TO UPDATE

										SECTION 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.2 AND 5.3 OF THE SMPC AND PIL IN LINE WITH COMPANY CORE DATA SHEET (CCDS V.16).
PL 18920/0037	PROHANCE INJECTION	GRANTED	PL 18920/0037-0006	PL 18920/0037-0006	11/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - NATIONAL WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE CLINICAL DATA REGARDING THE NEPHROGENIC SYSTEMIC FIBROSIS (NSF) IN PATIENTS RECEIVING GADOLINIUM-BASED CONTRAST AGENTS (GBCAS) IN LINE WITH ARTICLE 31 REFERRAL EMEA/H/A-31/1097.
PL 18920/0038	PROHANCE INJECTION	GRANTED	PL 18920/0038-0006	PL 18920/0038-0006	11/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - NATIONAL WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE CLINICAL DATA REGARDING THE NEPHROGENIC SYSTEMIC FIBROSIS (NSF) IN PATIENTS RECEIVING GADOLINIUM-BASED CONTRAST AGENTS (GBCAS) IN LINE WITH ARTICLE 31 REFERRAL EMEA/H/A-31/1097.
PL 18920/0039	MULTIHANCE 0.5M SOLUTION FOR INJECTION	GRANTED	PL 18920/0039-0011	PL 18920/0039-0011	11/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - NATIONAL WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE CLINICAL DATA REGARDING THE NEPHROGENIC SYSTEMIC FIBROSIS (NSF) IN PATIENTS RECEIVING GADOLINIUM-BASED CONTRAST AGENTS

										(GBCAS) IN LINE WITH ARTICLE 31 REFERRAL EMEA/H/A-31/1097.
PL 18920/0040	MULTIHANCE 529 MG/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 18920/0040-0011	PL 18920/0040-0011	11/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - NATIONAL WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE CLINICAL DATA REGARDING THE NEPHROGENIC SYSTEMIC FIBROSIS (NSF) IN PATIENTS RECEIVING GADOLINIUM-BASED CONTRAST AGENTS (GBCAS) IN LINE WITH ARTICLE 31 REFERRAL EMEA/H/A-31/1097.
PL 06492/0009	TANTUMGRIP LEMON FLAVOUR 600MG/10MG POWDER FOR ORAL SOLUTION	GRANTED	PL 06492/0009-0021	PL 06492/0009-0021	16/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE THE RISK MANAGEMENT PLAN
PL 06492/0010	TANTUMGRIP LEMON-HONEY FLAVOUR 600 MG/10 MG POWDER FOR ORAL SOLUTION	GRANTED	PL 06492/0010-0021	PL 06492/0010-0021	16/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE THE RISK MANAGEMENT PLAN
PL 06492/0011	TANTUMGRIP ORANGE FLAVOUR 600MG/10MG POWDER FOR ORAL SOLUTION	GRANTED	PL 06492/0011-0023	PL 06492/0011-0023	16/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE THE RISK MANAGEMENT PLAN
PL 04416/1040	CYPROTERONE ACETATE 2.0MG ETHINYLESTRADIOL 0.035MG TABLETS	GRANTED	PL 04416/1040-0028	PL 04416/1040-0028	20/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8, AND 4.9 OF THE SMPC TO THE NOT HARMONISED REFERENCE

								RD) - CMS		PRODUCT DIANE 35, JENAPHARM, DATED DECEMBER 2018 - THE REFERENCE PRODUCT THAT IS ADAPTED TO, IS THE REFERENCE PRODUCT FROM THE ORIGINAL APPLICATION WHICH IS DIANE 35, JENAPHARM. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 46602/0007	STAMARIL POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 46602/0007-0026	PL 46602/0007-0026	22/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTIONS 4.1, 4.2, 4.3, 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC IN ORDER TO REINFORCE THE USE OF STAMARIL IN ACCORDANCE WITH APPROVED INDICATION, FOLLOWING THE CONCLUSION AND RECOMMENDATION OF THE BENEFIT-RISK REVIEW CONDUCTED BY THE CHM EXPERT WORKING GROUP (EWG) IN THE UK. CONSEQUENTLY, THE PIL HAS BEEN UPDATED. [2] TO INTRODUCE AN UPDATED RMP (FROM RMP VERSION 3.0 TO

										RMP VERSION 3.1) TO ADD LOCAL RISK MINIMISATION MEASURES (RMM).
PL 46602/0007	STAMARIL POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 46602/0007-0026	PL 46602/0007-0026	22/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	[1] TO UPDATE SECTIONS 4.1, 4.2, 4.3, 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC IN ORDER TO REINFORCE THE USE OF STAMARIL IN ACCORDANCE WITH APPROVED INDICATION, FOLLOWING THE CONCLUSION AND RECOMMENDATION OF THE BENEFIT-RISK REVIEW CONDUCTED BY THE CHM EXPERT WORKING GROUP (EWG) IN THE UK. CONSEQUENTLY, THE PIL HAS BEEN UPDATED. [2] TO INTRODUCE AN UPDATED RMP (FROM RMP VERSION 3.0 TO RMP VERSION 3.1) TO ADD LOCAL RISK MINIMISATION MEASURES (RMM).
PL 04425/0041	RIFINAH 150/100MG TABLETS	GRANTED	PL 04425/0041-0107	PL 04425/0041-0107	23/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 AND 4.5 OF THE SMPC AND PIL FOR ALL ITS RIFAMPICIN CONTAINING PRODUCTS (INCLUDING

								WORKSHARING		RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/0042	RIFINAH 300/150MG COATED TABLETS	GRANTED	PL 04425/0042-0113	PL 04425/0042-0113	23/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 AND 4.5 OF THE SMPC AND PIL FOR ALL ITS RIFAMPICIN CONTAINING PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/0060	RIFATER TABLETS	GRANTED	PL 04425/0060-0109	PL 04425/0060-0109	23/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 AND 4.5 OF THE SMPC AND PIL FOR ALL ITS RIFAMPICIN CONTAINING PRODUCTS

								WORKSHARING		(INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/5915R	RIFADIN 150MG CAPSULES	GRANTED	PL 04425/5915R-0111	PL 04425/5915R-0111	23/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 AND 4.5 OF THE SMPC AND PIL FOR ALL ITS RIFAMPICIN CONTAINING PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/5916R	RIFADIN 300MG CAPSULES	GRANTED	PL 04425/5916R-0111	PL 04425/5916R-0111	23/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 AND 4.5 OF THE SMPC AND PIL FOR ALL ITS RIFAMPICIN CONTAINING

								CMS WORKSHARING		PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/5917R	RIFADIN 100MG/5ML ORAL SUSPENSION	GRANTED	PL 04425/5917R-0092	PL 04425/5917R-0092	23/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 AND 4.5 OF THE SMPC AND PIL FOR ALL ITS RIFAMPICIN CONTAINING PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04416/0956	TEPHINE 200 MICROGRAM SUBLINGUAL TABLETS	GRANTED	PL 04416/0956-0024	PL 04416/0956-0024	26/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.5 AND 4.8 OF THE SMPC AND PIL TO THE NOT

								RD) - CMS		HARMONISED REFERENCE PRODUCT TEMGESIC, SUBLINGUALE RESORIBLETTER, INDIVIOR, NATIONALLY AUTHORISED IN DENMARK (MA NUMBER 10658 AND 13628) DATED FEBRUARY 2020 .
PL 04416/0957	TEPHINE 400 MICROGRAM SUBLINGUAL TABLETS	GRANTED	PL 04416/0957-0024	PL 04416/0957-0024	26/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.2, 4.4, 4.5 AND 4.8 OF THE SMPC AND PIL TO THE NOT HARMONISED REFERENCE PRODUCT TEMGESIC, SUBLINGUALE RESORIBLETTER, INDIVIOR, NATIONALLY AUTHORISED IN DENMARK (MA NUMBER 10658 AND 13628) DATED FEBRUARY 2020 .
PL 15513/0396	SUDAFED SINUS PRESSURE & PAIN 200MG/30MG TABLETS	GRANTED	PL 15513/0396-0015	PL 15513/0396-0015	29/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.9 OF THE SPC IN LINE WITH THE LATEST COMPANY CORE DATA SHEET VERSION AND THE RECENT IBUPROFEN PRAC/CMDH RECOMMENDATION. THE PIL HAS ALSO BEEN UPDATED. **THE FINAL AGREED

										VERSIONS OF THE SPC SECTION 4.4 AND PIL HAVE BEEN RE-INDEXED INTO THE 'INPUT' FOLDER AS THESE DOCUMENTS HAVE BEEN SUBSEQUENTLY SUPERCEDED.**
PL 15513/0396	SUDAFED SINUS PRESSURE & PAIN 200MG/30MG TABLETS	GRANTED	PL 15513/0396-0015	PL 15513/0396-0015	29/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.9 OF THE SPC IN LINE WITH THE LATEST COMPANY CORE DATA SHEET VERSION AND THE RECENT IBUPROFEN PRAC/CMDH RECOMMENDATION. THE PIL HAS ALSO BEEN UPDATED. **THE FINAL AGREED VERSIONS OF THE SPC SECTION 4.4 AND PIL HAVE BEEN RE-INDEXED INTO THE 'INPUT' FOLDER AS THESE DOCUMENTS HAVE BEEN SUBSEQUENTLY SUPERCEDED.**
PL 15513/0396	SUDAFED SINUS PRESSURE & PAIN 200MG/30MG TABLETS	GRANTED	PL 15513/0396-0017	PL 15513/0396-0017	30/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH THE NEWEST VERSION OF THE COMPANY CORE DATA SHEET (VERSION 4.0). CONSEQUENTLY,

										IMPACTING THE PIL. **THE FINAL AGREED VERSION OF THE PIL HAS BEEN RE-INDEXED INTO THE 'INPUT' FOLDER AS THIS HAS SUBSEQUENTLY BEEN SUPERCEDED. SPC 4.4 ALSO INCLUDES CHANGES APPROVED IN SUBMISSION WITH 0028 (V13).**
PL 15513/0396	SUDAFED SINUS PRESSURE & PAIN 200MG/30MG TABLETS	GRANTED	PL 15513/0396-0020	PL 15513/0396-0020	30/12/2020	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL IN LINE WITH THE NEWEST VERSION OF THE COMPANY CORE DATA SHEET. **THE PIL HAS NOT BEEN INDEXED INTO M1 AS THIS HAS SUBSEQUENTLY BEEN SUPERCEDED. SPC 4.4 ALSO INCLUDES CHANGES APPROVED WITH SUBMISSION 0028 (V13).**
PL 04425/0629	CALCORT 6MG TABLETS	GRANTED	PL 04425/0629-0050	PL 04425/0629-0050	02/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC IN RELATION TO AN UPDATE OF INFORMATION ON TUMOR LYSIS SYNDROME FOR SYSTEMIC

										GLUCOCORTICOIDS (DEFLAZACORT, DEXAMETHASONE ACETATE, HYDROCORTISONE, METHYLPREDNISOLONE, PREDNISOLONE AND PREDNISONE). CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 16950/0136	BUTRANS 5 MICROGRAM/HOUR	GRANTED	PL 16950/0136-0069	PL 16950/0136-0069	06/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) T UPDATE SECTIONS 4.4 AND 48 OF THE SMPC OF BUTRANS 5, 10, 15 AND 20 MICROGRAM/HOUR, TRANSDERMAL PATCH TO INCLUDE THE WARNING AND UNDESIRABLE EFFECT ¿SLEEP APNOEA¿ WITH CONSEQUENTIAL UPDATE TO PATIENT INFORMATION LEAFLET.
PL 16950/0137	BUTRANS 10 MICROGRAM/HOUR	GRANTED	PL 16950/0137-0067	PL 16950/0137-0067	06/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) T UPDATE SECTIONS 4.4 AND 48 OF THE SMPC OF BUTRANS 5, 10, 15 AND 20 MICROGRAM/HOUR, TRANSDERMAL PATCH TO INCLUDE THE WARNING AND UNDESIRABLE EFFECT ¿SLEEP APNOEA¿

										WITH CONSEQUENTIAL UPDATE TO PATIENT INFORMATION LEAFLET.
PL 16950/0138	BUTRANS 20 MICROGRAM/HOUR	GRANTED	PL 16950/0138-0067	PL 16950/0138-0067	06/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) T UPDATE SECTIONS 4.4 AND 48 OF THE SMPC OF BUTRANS 5, 10, 15 AND 20 MICROGRAM/HOUR, TRANSDERMAL PATCH TO INCLUDE THE WARNING AND UNDESIRABLE EFFECT ¿SLEEP APNOEA¿ WITH CONSEQUENTIAL UPDATE TO PATIENT INFORMATION LEAFLET.
PL 16950/0349	BUTRANS 15 MICROGRAM/HOUR	GRANTED	PL 16950/0349-0031	PL 16950/0349-0031	06/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	1) T UPDATE SECTIONS 4.4 AND 48 OF THE SMPC OF BUTRANS 5, 10, 15 AND 20 MICROGRAM/HOUR, TRANSDERMAL PATCH TO INCLUDE THE WARNING AND UNDESIRABLE EFFECT ¿SLEEP APNOEA¿ WITH CONSEQUENTIAL UPDATE TO PATIENT INFORMATION LEAFLET.

PL 31644/0002	CARDIOXANE 500 MG, POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 31644/0002-0039	PL 31644/0002-0039	08/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RMP FOR CARDIOXANE FROM VERSION 1.4 TO VERSION 3.0 (DATED 23 SEPTEMBER 2020)
PL 04425/0722	LASYNAC 200MG/30MG FILM COATED TABLETS	GRANTED	PL 04425/0722-0015	PL 04425/0722-0015	11/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.8 OF THE SMPC TO ADD 'PHOTOSENSITIVITY REACTION' AS AN ADVERSE REACTION AS A CONSEQUENTIAL CHANGE TO A RECENT UPDATE OF THE COMPANY CORE DATA SHEET. CONSEQUENTLY, THE PIL HAS BEEN UPDATED. **FINAL PIL TEXT INDEXED IN 'INPUT' FOLDER, AS THIS HAS SUBSEQUENTLY BEEN UPDATED (SEE IB/53).**
PL 04425/0722	LASYNAC 200MG/30MG FILM COATED TABLETS	GRANTED	PL 04425/0722-0025	PL 04425/0722-0025	11/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SPC SECTIONS 4.2, 4.3, 4.4, 4.5, AND 4.8, LABELLING, AND PIL IN LINE WITH THE LAST VERSION OF THE COMPANY'S CORE LABELLING DOCUMENT

										(COMPANY CORE DATA SHEET VERSION 4) AND QRD TEMPLATE. **FINAL LABEL & PIL AND SPC FRAGMENTS 4.2, 4.4, 4.5 INDEXED IN 'INPUT' FOLDER, AS THESE HAVE SUBSEQUENTLY BEEN UPDATED (SEE IB/53).**
PL 50622/0026	EPLERENONE 50MG FILM-COATED TABLETS	GRANTED	PL 50622/0026-0002	PL 50622/0026-0002	12/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SPC TO UPDATE THE NSAIDS INTERACTION TEXT TO PROVIDE ADDITIONAL MEDICAL GUIDANCE.
PL 50622/0027	EPLERENONE 25MG FILM-COATED TABLETS	GRANTED	PL 50622/0027-0002	PL 50622/0027-0002	12/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SPC TO UPDATE THE NSAIDS INTERACTION TEXT TO PROVIDE ADDITIONAL MEDICAL GUIDANCE.
PL 50622/0028	INSPRA 25MG FILM-COATED TABLETS	GRANTED	PL 50622/0028-0006	PL 50622/0028-0006	12/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SPC TO UPDATE THE NSAIDS INTERACTION TEXT TO PROVIDE ADDITIONAL MEDICAL GUIDANCE.

PL 50622/0029	INSPRA 50MG FILM-COATED TABLETS	GRANTED	PL 50622/0029-0006	PL 50622/0029-0006	12/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SPC TO UPDATE THE NSAIDS INTERACTION TEXT TO PROVIDE ADDITIONAL MEDICAL GUIDANCE.
PL 04425/0170	SABRIL SACHET 0.5G	GRANTED	PL 04425/0170-0068	PL 04425/0170-0068	13/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC FRAGMENTS OF PRODUCT INFORMATION OF SABRIL TABLETS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04425/0171	SABRIL TABLETS 500MG	GRANTED	PL 04425/0171-0070	PL 04425/0171-0070	13/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC FRAGMENTS OF PRODUCT INFORMATION OF SABRIL TABLETS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 25215/0026	AMIODARONE HYDROCHLORIDE 50 MG/ML CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 25215/0026-0034	PL 25215/0026-0034	14/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.3, 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) WHICH REQUIRE TO BE

										FURTHER SUBSTANTIATED BY NEW ADDITIONAL DATA TO BE SUBMITTED BY THE MAH.
PL 17780/0306	LOPRAZOLAM 1MG TABLETS	GRANTED	PL 17780/0306-0051	PL 17780/0306-0051	19/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND PIL TO HARMONISE ¿SUICIDALITY - RELATED¿ IN ALL EU MEMBER STATES WHERE LOPRAZOLAM IS AUTHORIZED AS REQUESTED BY THE CMDH IN APRIL 2018. ADDITIONALLY SECTION 4.8 OF THE SMPC HAS BEEN UPDATED TO INCLUDE SEARCH FOR MHRA YELLOW CARD IN THE GOOGLE PLAY OR APPLE APP STORE.
PL 21597/0005	EPIVAL CR 300MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21597/0005-0046	PL 21597/0005-0046	19/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6 AND 4,9 OF THE SMPC AND PIL TO ADJUST HE TEXT ACCORDING TO A HARMONIZATION WITH ORIGINATOR PRODUCT, WHICH RESULTED IN A CCSI UPDATE, 2) TO UPDATE

										SECTIONS 4.8 AND 5.2 OF THE SMPC AND SECTION 4 OF PIL FOLLOWING PUBLIC ASSESSMENT REPORT FOR PAEDIATRIC STUDIES SUBMITTED IN ACCORDANCE WITH ARTICLE 45 OF REGULATION (EC) NO1901/2006.
PL 21597/0005	EPIVAL CR 300MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21597/0005-0046	PL 21597/0005-0046	19/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6 AND 4,9 OF THE SMPC AND PIL TO ADJUST HE TEXT ACCORDING TO A HARMONIZATION WITH ORIGINATOR PRODUCT, WHICH RESULTED IN A CCSI UPDATE, 2) TO UPDATE SECTIONS 4.8 AND 5.2 OF THE SMPC AND SECTION 4 OF PIL FOLLOWING PUBLIC ASSESSMENT REPORT FOR PAEDIATRIC STUDIES SUBMITTED IN ACCORDANCE WITH ARTICLE 45 OF REGULATION (EC) NO1901/2006.

PL 21597/0006	EPIVAL CR 500MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21597/0006-0044	PL 21597/0006-0044	19/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6 AND 4,9 OF THE SMPC AND PIL TO ADJUST HE TEXT ACCORDING TO A HARMONIZATION WITH ORIGINATOR PRODUCT, WHICH RESULTED IN A CCSI UPDATE, 2) TO UPDATE SECTIONS 4.8 AND 5.2 OF THE SMPC AND SECTION 4 OF PIL FOLLOWING PUBLIC ASSESSMENT REPORT FOR PAEDIATRIC STUDIES SUBMITTED IN ACCORDANCE WITH ARTICLE 45 OF REGULATION (EC) NO1901/2006.
PL 21597/0006	EPIVAL CR 500MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21597/0006-0044	PL 21597/0006-0044	19/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6 AND 4,9 OF THE SMPC AND PIL TO ADJUST HE TEXT ACCORDING TO A HARMONIZATION WITH ORIGINATOR PRODUCT, WHICH RESULTED IN A CCSI UPDATE,

										2) TO UPDATE SECTIONS 4.8 AND 5.2 OF THE SMPC AND SECTION 4 OF PIL FOLLOWING PUBLIC ASSESSMENT REPORT FOR PAEDIATRIC STUDIES SUBMITTED IN ACCORDANCE WITH ARTICLE 45 OF REGULATION (EC) NO1901/2006.
PL 46883/0001	OZALIN 2 MG/ML ORAL SOLUTION IN SINGLE-DOSE CONTAINER	GRANTED	PL 46883/0001-0008	PL 46883/0001-0008	20/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FROM RISK MANAGEMENT PLAN VERSION 4 TO RISK MANAGEMENT PLAN VERSION 5.
PL 08828/0167	FRESENIUS PROPOVEN 1%, EMULSION FOR INJECTION OR INFUSION	GRANTED	PL 08828/0167-0061	PL 08828/0167-0061	22/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN OF THE FINISHED PRODUCT.
PL 08828/0168	FRESENIUS PROPOVEN 2%	GRANTED	PL 08828/0168-0048	PL 08828/0168-0048	22/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN OF THE FINISHED PRODUCT.
PL 08828/0239	PROPOVEN 1% EMULSION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	GRANTED	PL 08828/0239-0030	PL 08828/0239-0030	22/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN OF THE FINISHED PRODUCT.

								CMS RMP		
PL 08828/0240	PROPOVEN 2% EMULSION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	GRANTED	PL 08828/0240-0024	PL 08828/0240-0024	22/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN OF THE FINISHED PRODUCT.
PL 16363/0256	QUINAPRIL/HYDROCHLOROTHIAZIDE 10/12.5 MG FILM-COATED TABLETS	GRANTED	PL 16363/0256-0041	PL 16363/0256-0041	23/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO REGISTER AN UPDATED RMP IN LINE WITH THE CURRENT ¿GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP) MODULE V - RISK MANAGEMENT SYSTEMS¿ AND THE ¿GUIDANCE ON FORMAT OF THE RISK MANAGEMENT PLAN (RMP) IN THE EU (V2.0.1).
PL 31745/0005	PIPERACILLIN/TAZOBACTAM 2 G/0.25 G POWDER FOR SOLUTION FOR INFUSION	GRANTED	PL 31745/0005-0073	PL 31745/0005-0073	24/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 1, 2, 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 5.2, 6.2 AND 6.6 OF THE SMPC FRAGMENTS IN LINE WITH THE SMPC & PIL OF THE REFERENCE PRODUCT TAZOCIN. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 31745/0006	PIPERACILLIN/TAZOBACTAM 4 G/0.5 G POWDER FOR	GRANTED	PL 31745/0	PL 31745/0	24/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II	DECENTRALISED	TO UPDATE SECTIONS 1, 2, 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 5.2, 6.2

	SOLUTION FOR INFUSION		006-0081	006-0081				(STANDARD) - CMS		AND 6.6 OF THE SMPC FRAGMENTS IN LINE WITH THE SMPC & PIL OF THE REFERENCE PRODUCT TAZOCIN. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04569/1752	CLINDAMYCIN 150 MG HARD CAPSULES	GRANTED	PL 04569/1752-0008	PL 04569/1752-0008	25/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.1 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT DALACINE 150 MG AND 300 MG, GÉLULE BY MAH (PFIZER HOLDING FRANCE).
PL 04569/1753	CLINDAMYCIN 300 MG HARD CAPSULES	GRANTED	PL 04569/1753-0009	PL 04569/1753-0009	25/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.6 AND 5.1 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT DALACINE 150 MG AND 300 MG, GÉLULE BY MAH (PFIZER HOLDING FRANCE).
PL 02855/0284	NICOTINE MINI 1.5 MG COMPRESSED LOZENGES	GRANTED	PL 02855/0284-0028	PL 02855/0284-0028	27/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE TEXT ENABLING NIQUITIN MINIS TO BE USED IN COMBINATION WITH NIQUITIN PATCHES IN SMPC, CORRESPONDING LEAFLET AND LABELLING.

										TO UPDATE TEXT RELATING TO UNDESIRABLE EFFECTS IN SECTION 4.8 OF THE SMPC AND CORRESPONDING PIL FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SECTION 4.8 OF THE SPC HAS BEEN UPDATED. TO DELETE TEXT RELATING TO FERTILITY IN SECTION 5.3 OF THE SMPC TO ALIGN WITH INFORMATION IN SECTION 4.6. CONSEQUENTLY, SECTION 5.3 OF THE SMPC HAS BEEN UPDATED.
PL 02855/0300	NICOTINE MINI 4 MG COMPRESSED LOZENGES	GRANTED	PL 02855/0300-0027	PL 02855/0300-0027	27/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE TEXT ENABLING NIQUITIN MINIS TO BE USED IN COMBINATION WITH NIQUITIN PATCHES IN SMPC, CORRESPONDING LEAFLET AND LABELLING.

										TO UPDATE TEXT RELATING TO UNDESIRABLE EFFECTS IN SECTION 4.8 OF THE SMPC AND CORRESPONDING PIL FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTLY, SECTION 4.8 OF THE SPC HAS BEEN UPDATED. TO DELETE TEXT RELATING TO FERTILITY IN SECTION 5.3 OF THE SMPC TO ALIGN WITH INFORMATION IN SECTION 4.6. CONSEQUENTLY, SECTION 5.3 OF THE SMPC HAS BEEN UPDATED.
PL 46602/0009	VIATIM, SUSPENSION AND SOLUTION FOR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 46602/0009-0033	PL 46602/0009-0033	27/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 4.4 AND 6.1 OF THE SMPC AND PIL TO COMPLY WITH THE 'GUIDELINE ON QUALITY ASPECTS INCLUDED IN THE PRODUCT INFORMATION FOR VACCINES FOR HUMAN USE' EMA/CHMP/BWP/13354

										0/2017 (DATED 18 OCTOBER 2018).
PL 11243/0002	MEDIKINET 5MG TABLETS	GRANTED	PL 11243/0002-0055	PL 11243/0002-0055	29/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENTS IN LINE WITH THE REFERENCE PRODUCT RITALIN WITH REGARDS TO THE POTENTIAL SIDE EFFECTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 11243/0003	MEDIKINET 10MG TABLETS	GRANTED	PL 11243/0003-0054	PL 11243/0003-0054	29/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENTS IN LINE WITH THE REFERENCE PRODUCT RITALIN WITH REGARDS TO THE POTENTIAL SIDE EFFECTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 11243/0004	MEDIKINET 20MG TABLETS	GRANTED	PL 11243/0004-0055	PL 11243/0004-0055	29/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENTS IN LINE WITH THE REFERENCE PRODUCT RITALIN WITH REGARDS TO THE POTENTIAL SIDE EFFECTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.

PL 11243/0005	MEDIKINET XL 10 MG MODIFIED-RELEASE CAPSULES, HARD	GRANTED	PL 11243/0005-0074	PL 11243/0005-0074	29/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENTS IN LINE WITH THE REFERENCE PRODUCT RITALIN WITH REGARDS TO THE POTENTIAL SIDE EFFECTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 11243/0006	MEDIKINET XL 20 MG MODIFIED-RELEASE CAPSULES, HARD	GRANTED	PL 11243/0006-0073	PL 11243/0006-0073	29/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENTS IN LINE WITH THE REFERENCE PRODUCT RITALIN WITH REGARDS TO THE POTENTIAL SIDE EFFECTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 11243/0007	MEDIKINET XL 30 MG MODIFIED-RELEASE CAPSULES, HARD	GRANTED	PL 11243/0007-0072	PL 11243/0007-0072	29/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENTS IN LINE WITH THE REFERENCE PRODUCT RITALIN WITH REGARDS TO THE POTENTIAL SIDE EFFECTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 11243/0008	MEDIKINET XL 40 MG MODIFIED-RELEASE CAPSULES, HARD	GRANTED	PL 11243/0	PL 11243/0	29/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENTS IN LINE

			008-0072	008-0072				(STANDARD) - CMS		WITH THE REFERENCE PRODUCT RITALIN WITH REGARDS TO THE POTENTIAL SIDE EFFECTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 11243/0010	MEDIKINET XL 5 MG MODIFIED-RELEASE CAPSULES, HARD	GRANTED	PL 11243/0010-0042	PL 11243/0010-0042	29/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENTS IN LINE WITH THE REFERENCE PRODUCT RITALIN WITH REGARDS TO THE POTENTIAL SIDE EFFECTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 11243/0011	MEDIKINET XL 50 MG MODIFIED-RELEASE CAPSULE, HARD	GRANTED	PL 11243/0011-0035	PL 11243/0011-0035	29/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENTS IN LINE WITH THE REFERENCE PRODUCT RITALIN WITH REGARDS TO THE POTENTIAL SIDE EFFECTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 11243/0012	MEDIKINET XL 60 MG MODIFIED-RELEASE CAPSULE, HARD	GRANTED	PL 11243/0012-0035	PL 11243/0012-0035	29/01/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC FRAGMENTS IN LINE WITH THE REFERENCE PRODUCT RITALIN WITH REGARDS TO

										THE POTENTIAL SIDE EFFECTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 00242/0192	DUROGESIC DTRANS 25 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0192-0152	PL 00242/0192-0152	01/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.8 AND 5.3 OF THE SMPC DUE TO THE AVAILABILITY OF NEW CLINICAL AND PHARMACOVIGILANCE DATA. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00242/0193	DUROGESIC DTRANS 50 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0193-0150	PL 00242/0193-0150	01/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.8 AND 5.3 OF THE SMPC DUE TO THE AVAILABILITY OF NEW CLINICAL AND PHARMACOVIGILANCE DATA. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00242/0194	DUROGESIC DTRANS 75 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0194-0148	PL 00242/0194-0148	01/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.8 AND 5.3 OF THE SMPC DUE TO THE AVAILABILITY OF NEW CLINICAL AND PHARMACOVIGILANCE DATA. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 00242/0195	DUROGESIC DTRANS 100 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0195-0149	PL 00242/0195-0149	01/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.8 AND 5.3 OF THE SMPC DUE TO THE AVAILABILITY OF NEW CLINICAL AND PHARMACOVIGILANCE DATA. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00242/0409	DUROGESIC DTRANS 12 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0409-0094	PL 00242/0409-0094	01/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.8 AND 5.3 OF THE SMPC DUE TO THE AVAILABILITY OF NEW CLINICAL AND PHARMACOVIGILANCE DATA. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 50622/0046	NEURONTIN 100MG HARD CAPSULES	GRANTED	PL 50622/0046-0009	PL 50622/0046-0009	01/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC TO STRENGTHEN THE LANGUAGE REGARDING THE CONCOMITANT ADMINISTRATION OF GABAPENTIN WITH OPIOID-CONTAINING DRUGS AND OTHER CNS DEPRESSANTS AND TO INCLUDE THE RISK OF FATAL RESPIRATORY DEPRESSION AND 4.5 OF THE SMPC TO STRENGTHEN THE

										LANGUAGE FOR THE RISK OF RESPIRATORY DEPRESSION, SEDATION, AND DEATH ASSOCIATED WITH GABAPENTIN WHEN CO ADMINISTERED WITH CNS DEPRESSANTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50622/0047	NEURONTIN 300MG HARD CAPSULES	GRANTED	PL 50622/0047-0009	PL 50622/0047-0009	01/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC TO STRENGTHEN THE LANGUAGE REGARDING THE CONCOMITANT ADMINISTRATION OF GABAPENTIN WITH OPIOID-CONTAINING DRUGS AND OTHER CNS DEPRESSANTS AND TO INCLUDE THE RISK OF FATAL RESPIRATORY DEPRESSION AND 4.5 OF THE SMPC TO STRENGTHEN THE LANGUAGE FOR THE RISK OF RESPIRATORY DEPRESSION, SEDATION, AND DEATH ASSOCIATED WITH GABAPENTIN WHEN CO ADMINISTERED WITH

										CNS DEPRESSANTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50622/0048	NEURONTIN 400MG HARD CAPSULES	GRANTED	PL 50622/0048-0009	PL 50622/0048-0009	01/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC TO STRENGTHEN THE LANGUAGE REGARDING THE CONCOMITANT ADMINISTRATION OF GABAPENTIN WITH OPIOID-CONTAINING DRUGS AND OTHER CNS DEPRESSANTS AND TO INCLUDE THE RISK OF FATAL RESPIRATORY DEPRESSION AND 4.5 OF THE SMPC TO STRENGTHEN THE LANGUAGE FOR THE RISK OF RESPIRATORY DEPRESSION, SEDATION, AND DEATH ASSOCIATED WITH GABAPENTIN WHEN CO ADMINISTERED WITH CNS DEPRESSANTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50622/0049	NEURONTIN 600MG FILM-COATED TABLETS	GRANTED	PL 50622/0049-0008	PL 50622/0049-0008	01/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC TO STRENGTHEN THE LANGUAGE REGARDING THE

								CMS WORKSHARING		CONCOMITANT ADMINISTRATION OF GABAPENTIN WITH OPIOID-CONTAINING DRUGS AND OTHER CNS DEPRESSANTS AND TO INCLUDE THE RISK OF FATAL RESPIRATORY DEPRESSION AND 4.5 OF THE SMPC TO STRENGTHEN THE LANGUAGE FOR THE RISK OF RESPIRATORY DEPRESSION, SEDATION, AND DEATH ASSOCIATED WITH GABAPENTIN WHEN CO ADMINISTERED WITH CNS DEPRESSANTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 50622/0050	NEURONTIN 800MG FILM-COATED TABLETS	GRANTED	PL 50622/0050-0008	PL 50622/0050-0008	01/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC TO STRENGTHEN THE LANGUAGE REGARDING THE CONCOMITANT ADMINISTRATION OF GABAPENTIN WITH OPIOID-CONTAINING DRUGS AND OTHER CNS DEPRESSANTS AND TO INCLUDE THE RISK OF FATAL RESPIRATORY

										DEPRESSION AND 4.5 OF THE SMPC TO STRENGTHEN THE LANGUAGE FOR THE RISK OF RESPIRATORY DEPRESSION, SEDATION, AND DEATH ASSOCIATED WITH GABAPENTIN WHEN CO ADMINISTERED WITH CNS DEPRESSANTS. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 00025/0588	ASMANEX TWISTHALER 200 MICROGRAMS INHALATION POWDER	GRANTED	PL 00025/0588-0045	PL 00025/0588-0045	02/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 1, 2, 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 5.1, 5.3 AND 6.5 OF THE SMPC FRAGMENTS TO ALIGN THE PRODUCT INFORMATION (PI) WITH THE ASMANEX TWISTHALER COMPANY CORE DATA SHEET (CCDS), IN PARTICULAR THE SECTION CONCERNING THE GLOBAL INITIATIVE FOR ASTHMA (GINA) 2019 GUIDELINES OF RINSING OF THE MOUTH WITH WATER AFTER USE. CONSEQUENTIALLY

										THE PIL HAS BEEN UPDATED.
PL 00025/0589	ASMANEX TWISTHALER 400 MICROGRAMS INHALATION POWDER	GRANTED	PL 00025/0589-0044	PL 00025/0589-0044	02/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 1, 2, 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 5.1, 5.3 AND 6.5 OF THE SMPC FRAGMENTS TO ALIGN THE PRODUCT INFORMATION (PI) WITH THE ASMANEX TWISTHALER COMPANY CORE DATA SHEET (CCDS), IN PARTICULAR THE SECTION CONCERNING THE GLOBAL INITIATIVE FOR ASTHMA (GINA) 2019 GUIDELINES OF RINSING OF THE MOUTH WITH WATER AFTER USE. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 44673/0135	NICOTINELL FRUIT 2MG, MEDICATED CHEWING-GUMS	GRANTED	PL 44673/0135-0013	PL 44673/0135-0013	03/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH THE GLOBAL SAFETY INFORMATION FOR NICOTINE GUM. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.

PL 44673/0136	NICOTINELL FRUIT 4 MG, MEDICATED CHEWING-GUMS	GRANTED	PL 44673/0136-0010	PL 44673/0136-0010	03/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH THE GLOBAL SAFETY INFORMATION FOR NICOTINE GUM. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 44673/0137	NICOTINELL LIQUORICE 2MG MEDICATED CHEWING GUM	GRANTED	PL 44673/0137-0008	PL 44673/0137-0008	03/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH THE GLOBAL SAFETY INFORMATION FOR NICOTINE GUM. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 44673/0138	NICOTINELL LIQUORICE 4MG MEDICATED CHEWING GUM	GRANTED	PL 44673/0138-0008	PL 44673/0138-0008	03/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH THE GLOBAL SAFETY INFORMATION FOR NICOTINE GUM. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 44673/0139	NICOTINELL ICE MINT 2 MG MEDICATED CHEWING-GUM	GRANTED	PL 44673/0139-0009	PL 44673/0139-0009	03/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH THE GLOBAL SAFETY INFORMATION FOR NICOTINE GUM. AS A CONSEQUENCE,

										THE PIL HAS BEEN UPDATED.
PL 44673/0140	NICOTINELL ICE MINT 4 MG MEDICATED CHEWING-GUM	GRANTED	PL 44673/0140-0009	PL 44673/0140-0009	03/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 AND 5.2 OF THE SMPC IN LINE WITH THE GLOBAL SAFETY INFORMATION FOR NICOTINE GUM. AS A CONSEQUENCE, THE PIL HAS BEEN UPDATED.
PL 06958/0031	AZZALURE, 125 SPEYWOOD UNITS, POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 06958/0031-0079	PL 06958/0031-0079	06/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.8 (UNDESIRABLE EFFECTS) OF THE SPC AND CONSEQUENTIALLY THE LEAFLET BY ADDING HYPOAESTHESIA AS AN ADVERSE EFFECT WITH THE UNKNOWN FREQUENCY.
PL 00063/0135	GAVISCON STRAWBERRY FLAVOUR CHEWABLE TABLETS	GRANTED	PL 00063/0135-0054	PL 00063/0135-0054	10/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.9 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS). ADDITIONAL UPDATES HAVE BEEN MADE IN LINE WITH THE EXCIPIENT GUIDELINES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.

PL 00063/0159	GAVISCON LIQUID SACHETS	GRANTED	PL 00063/0159-0045	PL 00063/0159-0045	10/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.9 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS). ADDITIONAL UPDATES HAVE BEEN MADE IN LINE WITH THE EXCIPIENT GUIDELINES. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 42714/0002	TESTOGEL 50 MG TRANSDERMAL GEL IN SACHET	GRANTED	PL 42714/0002-0010	PL 42714/0002-0010	12/02/2021	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, 8 AND 9 IN LINE WITH THE RESULT OF ROUTINE PHARMACOVIGILANCE LIFECYCLE MANAGEMENT REVIEW. CONSEQUENTLY, IMPACTING THE PIL.
PL 03194/0014	PICOLAX POWDER FOR ORAL SOLUTION	GRANTED	PL 03194/0014-0125	PL 03194/0014-0125	15/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, AND 5.1 OF THE SMPC, LABELLING AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET. ADDITIONALLY THE EDITORIAL MODIFICATIONS TO CDS HAS BEEN MADE O ALIGN IT WITH CURRENT GUIDANCE FOR SUMMARY OF

										PRODUCT CHARACTERISTICS (SMPC).
PL 00057/1496	VESIERRA 5 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 00057/1496-0027	PL 00057/1496-0027	16/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC IN LINE WITH THE MARKETING AUTHORISATION HOLDER´S COMPANY CORE DATA SHEET AND SECTIONS 4.5 AND 4.8 OF THE SMPC TO HARMONISE WITH BRITISH SPELLING.
PL 00057/1497	VESIERRA 25 MG/ML SOLUTION FOR INJECTION	GRANTED	PL 00057/1497-0030	PL 00057/1497-0030	16/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 OF THE SMPC IN LINE WITH THE MARKETING AUTHORISATION HOLDER´S COMPANY CORE DATA SHEET AND SECTIONS 4.5 AND 4.8 OF THE SMPC TO HARMONISE WITH BRITISH SPELLING.
PL 41042/0001	DUODOPA 20MG/ML + 5MG/ML, INTESTINAL GEL	GRANTED	PL 41042/0001-0057	PL 41042/0001-0057	18/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS GROUPING	MUTUAL RECOGNITION	TO REGISTER AN UPDATED RMP (FROM VERSION 8.0 TO VERSION 9.0) BASED ON THE IMPACT OF STUDY M12-927 (INSIGHT) ON DUODOPA'S RISK/BENEFIT RATIO AND RECATEGORISATION OF POLYNEUROPATHY AS A CONSEQUENCE OF SINGLE

										ASSESSMENT OF THE LAST PSUR BY PRAC.
PL 41042/0001	DUODOPA 20MG/ML + 5MG/ML, INTESTINAL GEL	GRANTED	PL 41042/0001-0057	PL 41042/0001-0057	18/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS GROUPING	MUTUAL RECOGNITION	TO REGISTER AN UPDATED RMP (FROM VERSION 8.0 TO VERSION 9.0) BASED ON THE IMPACT OF STUDY M12-927 (INSIGHT) ON DUODOPA'S RISK/BENEFIT RATIO AND RECATEGORISATION OF POLYNEUROPATHY AS A CONSEQUENCE OF SINGLE ASSESSMENT OF THE LAST PSUR BY PRAC.
PL 00142/1015	ASPIRIN TABLET 75MG	GRANTED	PL 00142/1015-0007	PL 00142/1015-0007	23/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	DECENTRALISED	***CTS CASE UPDATED 11/10/2019*** 1. TO HARMONISE THE SMPC FOR ASPIRIN 75 MG TABLETS IN LINE WITH PL 21597/0067 (MAH: G.L. PHARMA GMBH) DATED: 28/06/2018. 2. TO UPDATE THE DOSAGE IN LINE WITH THAT SPECIFIED IN BRITISH NATIONAL FORMULARY AND

										OTHER SMPCS FOR SIMILAR ASPIRIN PRODUCTS. 3. TO MAKE MINOR EDITORIAL UPDATES TO THE SMPC AND LEAFLET UPDATED IN LINE WITH THE LATEST QRD-TEMPLATE (VERSION 10.1, 06/2019). CONSEQUENTLY, SMPC SECTIONS 4.2, 4.3, 4.4, 4.5, 4.8, 5.1, 5.2 AND THE PIL HAVE BEEN UPDATED.
PL 00142/1015	ASPIRIN TABLET 75MG	GRANTED	PL 00142/1015-0007	PL 00142/1015-0007	23/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - RMS GROUPING	DECENTRALISED	***CTS CASE UPDATED 11/10/2019*** 1. TO HARMONISE THE SMPC FOR ASPIRIN 75 MG TABLETS IN LINE WITH PL 21597/0067 (MAH: G.L. PHARMA GMBH) DATED: 28/06/2018. 2. TO UPDATE THE DOSAGE IN LINE WITH

										THAT SPECIFIED IN BRITISH NATIONAL FORMULARY AND OTHER SMPCS FOR SIMILAR ASPIRIN PRODUCTS. 3. TO MAKE MINOR EDITORIAL UPDATES TO THE SMPC AND LEAFLET UPDATED IN LINE WITH THE LATEST QRD-TEMPLATE (VERSION 10.1, 06/2019). CONSEQUENTLY, SMPC SECTIONS 4.2, 4.3, 4.4, 4.5, 4.8, 5.1, 5.2 AND THE PIL HAVE BEEN UPDATED.
PL 21344/0002	NALTREXONE HYDROCHLORIDE 50 MG FILM-COATED TABLETS	GRANTED	PL 21344/0002-0031	PL 21344/0002-0031	23/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 01, 02, 03, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, ,07, 08 AND 09 OF THE SMPC AND PIL ACCORDING TO PSUR WORKSHARING PROCEDURE IE/H/PSUR/0028/002 AND IN LINE WITH THE LATEST EXCIPIENT GUIDELINE (WORDING

										FOR LACTOSE AS EXCIPIENT).
PL 04425/0748	IBUSAN 200MG CAPSULES, SOFT	GRANTED	PL 04425/0748-0004	PL 04425/0748-0004	25/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC 4-8 AND PIL DUE TO NEW CLINICAL DATA CONCERNING PHOTOSENSITIVITY AS AN ADR.
PL 04425/0749	IBUSAN 400MG CAPSULES, SOFT	GRANTED	PL 04425/0749-0004	PL 04425/0749-0004	25/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SMPC 4-8 AND PIL DUE TO NEW CLINICAL DATA CONCERNING PHOTOSENSITIVITY AS AN ADR.
PL 10673/0043	FIBRYGA 1G POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 10673/0043-0017	PL 10673/0043-0017	25/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.6, 4.8, 5.1, 5.2, 6.5 AND 6.6 OF THE SMPC AND PIL COMMENTS OF THE NEW CMS RECEIVED DURING THE MRP REPEAT USE PROCEDURE (DE/H1490010011E/01) OF FIBRYGA WHICH WAS POSITIVELY FINALIZED ON JUNE 08,2020.
PL 00057/0284	FELDENE 0.5% W/W GEL.	GRANTED	PL 00057/0284-0054	PL 00057/0284-0054	26/02/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS) FOR THE ADDITION OF DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS) SYNDROME.

PL 08081/0059	ELVANSE ADULT 30 MG CAPSULES, HARD	GRANTED	PL 08081/0059-0035	PL 08081/0059-0035	01/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 AND SECTION 2 OF THE PIL IN LINE WITH THE PRAC RECOMMENDATION FOR THE LISDEXAMFETAMINE PSUR REPORTING PERIOD 23-FEB-2018 TO 22-FEB-2019 (PSUSA/00010289/201902) WITH REGARDS TO THE RISKS OF LISDEXAMPHETAMINE, AMPHETAMINE AND DEXTROAMPHETAMINE EXPOSURE DURING PREGNANCY.
PL 08081/0060	ELVANSE ADULT 50 MG CAPSULES, HARD	GRANTED	PL 08081/0060-0037	PL 08081/0060-0037	01/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 AND SECTION 2 OF THE PIL IN LINE WITH THE PRAC RECOMMENDATION FOR THE LISDEXAMFETAMINE PSUR REPORTING PERIOD 23-FEB-2018 TO 22-FEB-2019 (PSUSA/00010289/201902) WITH REGARDS TO THE RISKS OF LISDEXAMPHETAMINE, AMPHETAMINE AND DEXTROAMPHETAMINE EXPOSURE DURING PREGNANCY.
PL 08081/0061	ELVANSE ADULT 70 MG CAPSULES, HARD	GRANTED	PL 08081/0	PL 08081/0	01/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 AND SECTION 2 OF THE PIL IN LINE WITH

			061-0036	061-0036				(STANDARD) - CMS		THE PRAC RECOMMENDATION FOR THE LISDEXAMFETAMINE PSUR REPORTING PERIOD 23-FEB-2018 TO 22-FEB-2019 (PSUSA/00010289/201902) WITH REGARDS TO THE RISKS OF LISDEXAMPHETAMINE, AMPHETAMINE AND DEXTROAMPHETAMINE EXPOSURE DURING PREGNANCY.
PL 10949/0340	ZYBAN 150 MG PROLONGED RELEASE TABLETS	GRANTED	PL 10949/0340-0097	PL 10949/0340-0097	01/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO FURTHER EVALUATE THE SIGNAL BETWEEN BUPROPION AND ALOPECIA. CONCLUSION: NO UPDATES TO PRODUCT INFORMATION CONSIDERED WARRANTED FROM DATA PRESENTED.
PL 46302/0033	FAVERIN 100MG FILM-COATED TABLETS	GRANTED	PL 46302/0033-0027	PL 46302/0033-0027	02/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.3 AND 4.5 OF THE SMPC FRAGMENTS DUE TO NEW PHARMACOVIGILANCE DATA (VARIATION CATEGORY C.I.4) FOR FLUVOXAMINE MALEATE AS A TYPE II

										VARIATION. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 46302/0034	FAVERIN 50MG FILM-COATED TABLETS	GRANTED	PL 46302/0034-0024	PL 46302/0034-0024	02/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.3 AND 4.5 OF THE SMPC FRAGMENTS DUE TO NEW PHARMACOVIGILANCE DATA (VARIATION CATEGORY C.I.4) FOR FLUVOXAMINE MALEATE AS A TYPE II VARIATION. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 00057/1296	ZOTON FASTAB 15MG	GRANTED	PL 00057/1296-0028	PL 00057/1296-0028	02/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.2 AND 5.3 OF THE SMPC FRAGMENTS OF THE PRODUCT INFORMATION OF ZOTON FASTAB IN LINE WITH THE LATEST UPDATE TO THE COMPANY CORE DATA SHEET (CCDS 25.0) PREPARED BY TAKEDA UNDER PHARMACOVIGILANCE AGREEMENT. EDITORIAL CHANGES WERE MADE TO SPC SECTIONS 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 AND 6.1.

PL 00057/1297	ZOTON FASTAB 30MG	GRANTED	PL 00057/1297-0028	PL 00057/1297-0028	02/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.2 AND 5.3 OF THE SMPC FRAGMENTS OF THE PRODUCT INFORMATION OF ZOTON FASTAB IN LINE WITH THE LATEST UPDATE TO THE COMPANY CORE DATA SHEET (CCDS 25.0) PREPARED BY TAKEDA UNDER PHARMACOVIGILANCE AGREEMENT. EDITORIAL CHANGES WERE MADE TO SPC SECTIONS 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 AND 6.1.
PL 34078/0011	CUVITRU 200 MG/ML SOLUTION FOR SUBCUTANEOUS INJECTION	GRANTED	PL 34078/0011-0047	PL 34078/0011-0047	03/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE RMP FROM VERSION 1.1 TO VERSION 2.0 FOLLOWING A REASSESSMENT OF THE CLASSIFICATION OF RISK FOR ASEPTIC MENINGITIS. ASEPTIC MENINGITIS SYNDROME HAS BEEN UPGRADED FROM AN IMPORTANT POTENTIAL RISK TO AN IMPORTANT IDENTIFIED RISK IN THE RMP AND CONSEQUENTIALLY, SECTIONS 4.4 AND 4.8 OF THE SPC AND THE PIL TEXT HAVE BEEN UPDATED.

PL 40546/0114	ONDANSETRON 4 MG ORODISPERSIBLE TABLETS	GRANTED	PL 40546/0114-0009	PL 40546/0114-0009	03/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO REGISTER CHANGES TO FRAGMENTS 2, 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 IN ACCORDANCE WITH PSUSA (PSUSA/00002217/201502). CONSEQUENTIALLY, THE LEAFLET HAS ALSO BEEN UPDATED. 2. TO REGISTER CHANGES TO FRAGMENTS 2, 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 IN ACCORDANCE TO THE REFERENCE PRODUCT - ZOFRAN. CONSEQUENTIALLY, THE LEAFLET HAS ALSO BENE UPDATED.
PL 40546/0114	ONDANSETRON 4 MG ORODISPERSIBLE TABLETS	GRANTED	PL 40546/0114-0009	PL 40546/0114-0009	03/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO REGISTER CHANGES TO FRAGMENTS 2, 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 IN ACCORDANCE WITH PSUSA (PSUSA/00002217/201502). CONSEQUENTIALLY,

										THE LEAFLET HAS ALSO BEEN UPDATED. 2. TO REGISTER CHANGES TO FRAGMENTS 2, 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 IN ACCORDANCE TO THE REFERENCE PRODUCT - ZOFRAN. CONSEQUENTIALLY, THE LEAFLET HAS ALSO BENE UPDATED.
PL 40546/0115	ONDANSETRON 8 MG ORODISPERSIBLE TABLETS	GRANTED	PL 40546/0115-0010	PL 40546/0115-0010	03/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO REGISTER CHANGES TO FRAGMENTS 2, 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 IN ACCORDANCE WITH PSUSA (PSUSA/00002217/201502). CONSEQUENTIALLY, THE LEAFLET HAS ALSO BEEN UPDATED. 2. TO REGISTER CHANGES TO FRAGMENTS 2, 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 IN

										ACCORDANCE TO THE REFERENCE PRODUCT - ZOFRAN. CONSEQUENTIALLY, THE LEAFLET HAS ALSO BENE UPDATED.
PL 40546/0115	ONDANSETRON 8 MG ORODISPERSIBLE TABLETS	GRANTED	PL 40546/0115-0010	PL 40546/0115-0010	03/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO REGISTER CHANGES TO FRAGMENTS 2, 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 IN ACCORDANCE WITH PSUSA (PSUSA/00002217/201502). CONSEQUENTIALLY, THE LEAFLET HAS ALSO BEEN UPDATED. 2. TO REGISTER CHANGES TO FRAGMENTS 2, 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 IN ACCORDANCE TO THE REFERENCE PRODUCT - ZOFRAN. CONSEQUENTIALLY, THE LEAFLET HAS ALSO BENE UPDATED.
PL 00057/1448	VORICONAZOLE PFIZER 50 MG FILM-COATED TABLETS	GRANTED	PL 00057/1448-0026	PL 00057/1448-0026	08/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO INCLUDE ADDITIONAL TEXT IN THE SMPC REGARDING INTERACTION

								CMS WORKSHARING		BETWEEN VORICONAZOLE AND LETERMOVIR & TOLVAPTAN IN THE INTERACTION TABLE IN SECTION 4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
PL 00057/1449	VORICONAZOLE PFIZER 200 MG FILM-COATED TABLETS	GRANTED	PL 00057/1449-0028	PL 00057/1449-0028	08/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INCLUDE ADDITIONAL TEXT IN THE SMPC REGARDING INTERACTION BETWEEN VORICONAZOLE AND LETERMOVIR & TOLVAPTAN IN THE INTERACTION TABLE IN SECTION 4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
PL 00057/1450	VORICONAZOLE PFIZER 40 MG/ML POWDER FOR ORAL SUSPENSION	GRANTED	PL 00057/1450-0026	PL 00057/1450-0026	08/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INCLUDE ADDITIONAL TEXT IN THE SMPC REGARDING INTERACTION BETWEEN VORICONAZOLE AND LETERMOVIR & TOLVAPTAN IN THE INTERACTION TABLE

										IN SECTION 4.5 INTERAC TION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
PL 00057/1 451	VORICONAZOLE PFIZER 200 MG POWDER FOR SOLUTION FOR INFUSION	GRAN TED	PL 00057/1 451- 0032	PL 00057/1 451- 0032	08/03/ 2021	VARIA TION	TYPE II	VARV MEDICAL TYPE II (STANDA RD) - CMS WORKSH ARING	MUTUAL RECOGNI TION	TO INCLUDE ADDITIONAL TEXT IN THE SMPC REGARDING INTERACTION BETWEEN VORICONAZOLE AND LETERMOVIR & TOLVAPTAN IN THE INTERACTION TABLE IN SECTION 4.5 INTERAC TION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
PL 16950/0 157	TARGINACT 10 MG/5 MG PROLONGED-RELEASE TABLETS	GRAN TED	PL 16950/0 157- 0091	PL 16950/0 157- 0091	10/03/ 2021	VARIA TION	TYPE II	VARV MEDICAL TYPE II (STANDA RD) - CMS WORKSH ARING	DECENTR ALISED	1) TO UPDATE SECTIONS 4.4 AND 4.8 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS) AND SECTIONS 4.4 AND 4.5 OF THE SMPC AND PIL HAS BEEN UPDATED TO HARMONISE AND ALIGN THE TEXTS AFTER OPIODAL PRODUCTS CCDS REVIEW.

PL 16950/0158	TARGINACT 20 MG/10 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 16950/0158-0090	PL 16950/0158-0090	10/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	1) TO UPDATE SECTIONS 4.4 AND 4.8 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS) AND SECTIONS 4.4 AND 4.5 OF THE SMPC AND PIL HAS BEEN UPDATED TO HARMONISE AND ALIGN THE TEXTS AFTER OPIODAL PRODUCTS CCDS REVIEW.
PL 16950/0161	TARGINACT 40 MG/20 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 16950/0161-0087	PL 16950/0161-0087	10/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	1) TO UPDATE SECTIONS 4.4 AND 4.8 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS) AND SECTIONS 4.4 AND 4.5 OF THE SMPC AND PIL HAS BEEN UPDATED TO HARMONISE AND ALIGN THE TEXTS AFTER OPIODAL PRODUCTS CCDS REVIEW.
PL 16950/0162	TARGINACT 5 MG/2.5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 16950/0162-0091	PL 16950/0162-0091	10/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	1) TO UPDATE SECTIONS 4.4 AND 4.8 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS) AND SECTIONS 4.4 AND 4.5 OF THE SMPC AND PIL HAS BEEN UPDATED TO

										HARMONISE AND ALIGN THE TEXTS AFTER OPIODAL PRODUCTS CCDS REVIEW.
PL 16950/0162	TARGINACT 5 MG/2.5 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 16950/0162-0091	PL 16950/0162-0091	10/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	1) TO UPDATE SECTIONS 4.4 AND 4.8 AND PIL IN LINE WITH THE COMPANY CORE DATA SHEET (CCDS) AND SECTIONS 4.4 AND 4.5 OF THE SMPC AND PIL HAS BEEN UPDATED TO HARMONISE AND ALIGN THE TEXTS AFTER OPIODAL PRODUCTS CCDS REVIEW.
PL 00025/0546	ZISPIN SOLTAB 15MG ORODISPERSIBLE TABLET	GRANTED	PL 00025/0546-0029	PL 00025/0546-0029	15/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SPC IN LINE WITH PRAC RECOMMENDATIONS ON AMNESIA. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED. IN ADDITION, THE MAH HAS UPDATED THE LIST OF MEMBER STATES ASSOCIATED INVENTED NAMES IN SECTION 6 OF THE PACKAGE LEAFLET

										FURTHER TO LICENSE WITHDRAWALS IN DENMARK AND ICELAND.
PL 00025/0547	ZISPIN SOLTAB 30MG ORODISPERSIBLE TABLET	GRANTED	PL 00025/0547-0030	PL 00025/0547-0030	15/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SPC IN LINE WITH PRAC RECOMMENDATIONS ON AMNESIA. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED. IN ADDITION, THE MAH HAS UPDATED THE LIST OF MEMBER STATES ASSOCIATED INVENTED NAMES IN SECTION 6 OF THE PACKAGE LEAFLET FURTHER TO LICENSE WITHDRAWALS IN DENMARK AND ICELAND.
PL 00025/0548	ZISPIN SOLTAB 45MG ORODISPERSIBLE TABLET	GRANTED	PL 00025/0548-0029	PL 00025/0548-0029	15/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 OF THE SPC IN LINE WITH PRAC RECOMMENDATIONS ON AMNESIA. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED. IN ADDITION, THE MAH HAS UPDATED THE

										LIST OF MEMBER STATES ASSOCIATED INVENTED NAMES IN SECTION 6 OF THE PACKAGE LEAFLET FURTHER TO LICENSE WITHDRAWALS IN DENMARK AND ICELAND.
PL 00025/0546	ZISPIN SOLTAB 15MG ORODISPERSIBLE TABLET	GRANTED	PL 00025/0546-0025	PL 00025/0546-0025	17/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.4 AND 4.8 OF THE SMPC AND PIL IN COMPLIANCE WITH THE REVISED ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON `EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE' WHICH WAS UPDATED IN OCTOBER 2017. THESE CHANGES APPLY TO THE SMPC, PACKAGE LEAFLET AND LABELLING COMPONENTS. ALSO TO UPDATE SECTION 4.8 OF THE SMPC TO ADD ¿PRIAPISM¿ AND THE CONSEQUENTIAL CHANGE TO THE PIL.
PL 00025/0547	ZISPIN SOLTAB 30MG ORODISPERSIBLE TABLET	GRANTED	PL 00025/0547-0025	PL 00025/0547-0025	17/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.4 AND 4.8 OF THE SMPC AND PIL IN COMPLIANCE WITH

								RD) - CMS		THE REVISED ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON `EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE' WHICH WAS UPDATED IN OCTOBER 2017. THESE CHANGES APPLY TO THE SMPC, PACKAGE LEAFLET AND LABELLING COMPONENTS. ALSO TO UPDATE SECTION 4.8 OF THE SMPC TO ADD ¿PRIAPISM¿ AND THE CONSEQUENTIAL CHANGE TO THE PIL.
PL 00025/0548	ZISPIN SOLTAB 45MG ORODISPERSIBLE TABLET	GRANTED	PL 00025/0548-0025	PL 00025/0548-0025	17/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.4 AND 4.8 OF THE SMPC AND PIL IN COMPLIANCE WITH THE REVISED ANNEX TO THE EUROPEAN COMMISSION GUIDELINE ON `EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE' WHICH WAS UPDATED IN OCTOBER 2017. THESE CHANGES

										APPLY TO THE SMPC, PACKAGE LEAFLET AND LABELLING COMPONENTS. ALSO TO UPDATE SECTION 4.8 OF THE SMPC TO ADD ¿PRIAPISM¿ AND THE CONSEQUENTIAL CHANGE TO THE PIL.
PL 00010/0587	JAYDESS 13.5 MG INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 00010/0587-0045	PL 00010/0587-0045	17/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	DECENTRALISED	TO INTRODUCE/CHANGE THE OBLIGATIONS AND CONDITIONS OF A MARKETING AUTHORISATION, INCLUDING THE RISK MANAGEMENT PLAN.
PL 04425/0624	ZIMOVANE 7.5MG FILM-COATED TABLETS	GRANTED	PL 04425/0624-0070	PL 04425/0624-0070	18/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE INFORMATION REGARDING COMPLEX SLEEP BEHAVIOURS, SOME RESULTING IN SERIOUS INJURIES, INCLUDING DEATH AND CONSEQUENTLY TO UPDATE THE FOLLOWING SECTIONS 4.3, 4.4 AND 4.8 OF THE SMPC AND PIL TO ACHIEVE AN HARMONIZED OUTCOME IN ALL EU MEMBERS STATES WHERE ZOPICLONE IS AUTHORIZED.
PL 04425/0625	ZIMOVANE LS 3.75MG FILM-COATED TABLETS	GRANTED	PL 04425/0625-0069	PL 04425/0625-0069	18/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE THE INFORMATION REGARDING COMPLEX SLEEP BEHAVIOURS,

								RD) - CMS WORKSHARING		SOME RESULTING IN SERIOUS INJURIES, INCLUDING DEATH AND CONSEQUENTLY TO UPDATE THE FOLLOWING SECTIONS 4.3, 4.4 AND 4.8 OF THE SMPC AND PIL TO ACHIEVE AN HARMONIZED OUTCOME IN ALL EU MEMBERS STATES WHERE ZOPICLONE IS AUTHORIZED.
PL 16950/0167	FLUTIFORM 50 MICROGRAM / 5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0167-0064	PL 16950/0167-0064	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY

										CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING

										COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0167	FLUTIFORM 50 MICROGRAM / 5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0167-0064	PL 16950/0167-0064	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2

										AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE

										SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0168	FLUTIFORM 125 MICROGRAM / 5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0168-0063	PL 16950/0168-0063	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR

										SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL

										STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.

PL 16950/0168	FLUTIFORM 125 MICROGRAM / 5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0168-0063	PL 16950/0168-0063	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS

										ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000

										PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0169	FLUTIFORM 250 MICROGRAM / 10 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0169-0063	PL 16950/0169-0063	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT

										THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER

										2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0169	FLUTIFORM 250 MICROGRAM / 10 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0169-0063	PL 16950/0169-0063	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS

										PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN

										ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0185	AFFERA 50 MICROGRAM / 5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0185-0042	PL 16950/0185-0042	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28

										MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A

										SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0185	AFFERA 50 MICROGRAM / 5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0185-0042	PL 16950/0185-0042	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE

								WORKSHARING		REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-

										SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT

										IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0186	AFFERA 125 MICROGRAM/5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION.	GRANTED	PL 16950/0186-0042	PL 16950/0186-0042	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN

										OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY

										AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0186	AFFERA 125 MICROGRAM/5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION.	GRANTED	PL 16950/0186-0042	PL 16950/0186-0042	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP.

										ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK

										MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0187	AFFERA 250 MICROGRAM/10 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0187-0041	PL 16950/0187-0041	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01).

										FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST

										AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0187	AFFERA 250 MICROGRAM/10 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0187-0041	PL 16950/0187-0041	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND

										REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY

										AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0338	FLUTIFORM K-HALER 50 MICROGRAM/5 MICROGRAM PER ACTUATION	GRANTED	PL 16950/0338-0022	PL 16950/0338-0022	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3)

	PRESSURISED INHALATION, SUSPENSION							RD) - CMS WORKSHARING		AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION.

										TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER

										NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0338	FLUTIFORM K-HALER 50 MICROGRAM/5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0338-0022	PL 16950/0338-0022	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION

										(APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF

										ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0339	FLUTIFORM K-HALER 125 MICROGRAM/5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0339-0021	PL 16950/0339-0021	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018 REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF

										THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMOTEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED

										IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 16950/0339	FLUTIFORM K-HALER 125 MICROGRAM/5 MICROGRAM PER ACTUATION PRESSURISED INHALATION, SUSPENSION	GRANTED	PL 16950/0339-0021	PL 16950/0339-0021	19/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) (FROM VERSION 4.1 TO VERSION 4.3) AS PART OF A POST APPROVAL COMMITMENT OF THE REPEAT USE PROCEDURE FOR SE/H/1921/001-005/E/002 ACCORDING TO THE SECOND REVISED RMP GUIDANCE DOCUMENTS (28 MARCH 2017, EMA/838713/2011 REV2 AND 31 OCTOBER 2018, EMA/164/2018

										REV 2.01). FURTHERMORE, AS A RESULT OF PASS STUDIES, IT IS PROPOSED TO REMOVE SAFETY CONCERNS IN THIS UPDATED VERSION OF THE RMP. ADDITIONALLY, THE RMP HAS BEEN UPDATED TO REFLECT THE WORDING OF AN ALREADY APPROVED PAEDIATRIC INDICATION (APPROVAL IN OCTOBER 2018). ALL PRODUCT INFORMATION HAS ALREADY BEEN UPDATED TO REFLECT THE PAEDIATRIC INDICATION. TO PROVIDE THREE COMPLETED MAH-SPONSORED NON-INTERVENTIONAL STUDIES (FLT9501, FLT9503, FLT9508) WITH THE PRIMARY AIM OF IDENTIFYING, CHARACTERIZING OR QUANTIFYING A SAFETY HAZARD OR CONFIRMING THE SAFETY PROFILE OF FLUTICASONE/FORMO

										TEROL. THESE POST AUTHORISATION STUDIES (PASS), WERE CONDUCTED IN ORDER TO COMPLETE POST-MARKETING COMMITMENTS ORIGINALLY AGREED IN THE EU RISK MANAGEMENT PLAN (RMP VERSION 2.0, DATED 9TH OCTOBER 2013).DATA FROM FLT9501 AND FLT9503 WERE POOLED WITH THE AIM OF ANALYSING SAFETY AND EFFICACY DATA FROM APPROXIMATELY 4000 PATIENTS TREATED WITH FLUTICASONE/FORMOTEROL UNDER NORMAL CONDITIONS OF USE. THIS REPORT IS PROVIDED AS AN ADDITION TO FLT 9501.
PL 10592/0085	REQUIP 0.25MG	GRANTED	PL 10592/0085-0118	PL 10592/0085-0118	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE

										PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0085	REQUIP 0.25MG	GRANTED	PL 10592/0085-0118	PL 10592/0085-0118	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE.

										ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0085	REQUIP 0.25MG	GRANTED	PL 10592/0085-0118	PL 10592/0085-0118	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE

										ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0087	REQUIP 1MG	GRANTED	PL 10592/0087-0127	PL 10592/0087-0127	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0087	REQUIP 1MG	GRANTED	PL 10592/0087-0127	PL 10592/0087-0127	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK

								RD) - CMS WORKSHARING		GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0087	REQUIP 1MG	GRANTED	PL 10592/0087-0127	PL 10592/0087-0127	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/20190

										7 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0088	REQUIP 2MG	GRANTED	PL 10592/0088-0117	PL 10592/0088-0117	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME

										MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0088	REQUIP 2MG	GRANTED	PL 10592/0088-0117	PL 10592/0088-0117	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE

										PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0088	REQUIP 2MG	GRANTED	PL 10592/0088-0117	PL 10592/0088-0117	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0296	REQUIP XL 8 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0296-0061	PL 10592/0296-0061	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET

								CMS WORKSHARING		(GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0296	REQUIP XL 8 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0296-0061	PL 10592/0296-0061	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02

										AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0296	REQUIP XL 8 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0296-0061	PL 10592/0296-0061	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL

										UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 19494/0033	ADARTREL 0.25 MG FILM-COATED TABLETS	GRANTED	PL 19494/0033-0076	PL 19494/0033-0076	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS

										AGREED WITH ANSM (RMS).
PL 19494/0033	ADARTREL 0.25 MG FILM-COATED TABLETS	GRANTED	PL 19494/0033-0076	PL 19494/0033-0076	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 19494/0033	ADARTREL 0.25 MG FILM-COATED TABLETS	GRANTED	PL 19494/0033-0076	PL 19494/0033-0076	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET

								CMS WORKSHARING		(GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0089	REQUIP 5MG	GRANTED	PL 10592/0089-0113	PL 10592/0089-0113	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02

										AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0089	REQUIP 5MG	GRANTED	PL 10592/0089-0113	PL 10592/0089-0113	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL

										UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0089	REQUIP 5MG	GRANTED	PL 10592/0089-0113	PL 10592/0089-0113	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS

										AGREED WITH ANSM (RMS).
PL 10592/0293	REQUIP XL 2 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0293-0067	PL 10592/0293-0067	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0293	REQUIP XL 2 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0293-0067	PL 10592/0293-0067	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET

								CMS WORKSHARING		(GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0293	REQUIP XL 2 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0293-0067	PL 10592/0293-0067	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02

										AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0295	REQUIP XL 4 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0295-0062	PL 10592/0295-0062	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL

										UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 10592/0295	REQUIP XL 4 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0295-0062	PL 10592/0295-0062	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS

										AGREED WITH ANSM (RMS).
PL 10592/0295	REQUIP XL 4 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 10592/0295-0062	PL 10592/0295-0062	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 19494/0034	ADARTREL 0.5 MG FILM-COATED TABLETS	GRANTED	PL 19494/0034-0076	PL 19494/0034-0076	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET

								CMS WORKSHARING		(GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 19494/0034	ADARTREL 0.5 MG FILM-COATED TABLETS	GRANTED	PL 19494/0034-0076	PL 19494/0034-0076	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02

										AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 19494/0034	ADARTREL 0.5 MG FILM-COATED TABLETS	GRANTED	PL 19494/0034-0076	PL 19494/0034-0076	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL

										UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 19494/0036	ADARTREL 2 MG FILM-COATED TABLETS	GRANTED	PL 19494/0036-0072	PL 19494/0036-0072	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS

										AGREED WITH ANSM (RMS).
PL 19494/0036	ADARTREL 2 MG FILM-COATED TABLETS	GRANTED	PL 19494/0036-0072	PL 19494/0036-0072	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET (GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 19494/0036	ADARTREL 2 MG FILM-COATED TABLETS	GRANTED	PL 19494/0036-0072	PL 19494/0036-0072	23/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4, 4.8 OF SPC & SECTION 2 & 4 OF PIL IN LINE WITH GSK GLOBAL DATASHEET

								CMS WORKSHARING		(GDS), SECTION 4.4 OF THE SMPC AND PIL LINE WITH THE PRAC UPDATE REQUESTED TO THE DAWS TEXT DURING THE PSUSA/00002661/201907 AND SECTIONS 02 AND 4.4 OF THE SMPC AND SECTION 2 OF PIL TO BRING THE TEXT/FORMATTING IN LINE WITH THE EXCIPIENT GUIDELINE. ADDITIONALLY SOME MINOR EDITORIAL UPDATES FOR EXAMPLE ADDITION OF EXTRA COMMAS OR UNDERLINING OF HEADINGS ETC. TO THE M1.3.1 FOR THE ROPINIROLE PRODUCTS AS AGREED WITH ANSM (RMS).
PL 00063/0136	GAVISCON PEPPERMINT TABLETS 500	GRANTED	PL 00063/0136-0053	PL 00063/0136-0053	24/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SPC (SECTIONS 2, 4.4, 4.8, 4.9), AND CONSEQUENTIALLY THE PIL AND LABEL, TO INCORPORATE NEW SAFETY INFORMATION IN LINE WITH THE CCDS AND TO ALIGN WITH THE ANNEX TO THE EC GUIDELINE ON 'EXCIPIENTS IN THE

										LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCT FOR HUMAN USE' (SANTE-2017-11668) AND QRD TEMPLATE.
PL 04854/0157	BENILEXA 20 MICROGRAMS/24 HOURS INTRAUTERINE DELIVERY SYSTEM	GRANTED	PL 04854/0157-0032	PL 04854/0157-0032	26/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO REGISTER THE SUBMISSION OF THE FINAL PASS STUDY REPORT: ACTIVE POST-MARKETING SURVEILLANCE OF LEVONORGESTRELIUS INSERTION-RELATED DIFFICULTIES: A NON-INTERVENTIONAL POST-AUTHORISATION SAFETY STUDY (STUDY NO. EUPAS7857). CONSEQUENTIALLY, THE RMP HAS BEEN UPDATED FROM VERSION 8.5 TO VERSION 8.6.
PL 04515/0215	OXALIPLATIN HOSPIRA 5 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 04515/0215-0068	PL 04515/0215-0068	31/03/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC IN LINE WITH FOLLOWING ROUTINE PHARMACOVIGILANCE REVIEW OF DATA AVAILABLE IN THE PFIZER'S SAFETY DATABASE AND SUBSEQUENT EVALUATION OF

										INFORMATION ON THIS TOPIC THAT IS AVAILABLE IN THE PUBLISHED LITERATURE ALSO IS AN ADDITION OF A WARNING ON IMMUNOSUPPRESSANT EFFECTS/INCREASED SUSCEPTIBILITY TO INFECTIONS ASSOCIATED WITH VACCINES TO THE OXALIPLATIN EU. A TEXT VERSION OF THE UPDATED PIL HAS BEEN APPROVED. THE MAH HAS MADE A COMMITMENT TO SUBMIT A FULL COLOUR MOCK-UP OF PIL SEPARATELY TO PIQU.
PL 18753/0001	GLIADEL 7.7 MG IMPLANT	GRANTED	PL 18753/0001-0070	PL 18753/0001-0070	06/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL IN LINE WITH THE RECOMMENDATIONS OUTLINED IN THE FINAL PSUR ASSESSMENT REPORT FOR PSUSA/00010348/201809.
PL 35728/0001	RETROVIR CAPSULES 100MG	GRANTED	PL 35728/0001-0048	PL 35728/0001-0048	07/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.9 OF THE SMPC

								RD) - CMS GROUPING		-UPDATING ZIDOVUDINE OVERDOSAGE INFORMATION, IMPACTING SMPC SECTION 4.9 (¿OVERDOSE¿) AND PACKAGE LEAFLET; -UPDATING EXCIPIENT INFORMATION IN ALIGNMENT WITH EMA GUIDELINE, IMPACTING SMPC SECTION 2 (¿QUALITATIVE AND QUANTITATIVE COMPOSITION¿), SMPC SECTION 4.4 (¿SPECIAL WARNINGS AND PRECAUTIONS FOR USE¿), LABELLING AND PACKAGE LEAFLET.
PL 35728/0002	RETROVIR CAPSULES 250MG	GRANTED	PL 35728/0002-0046	PL 35728/0002-0046	07/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.9 OF THE SMPC -UPDATING ZIDOVUDINE OVERDOSAGE INFORMATION, IMPACTING SMPC SECTION 4.9 (¿OVERDOSE¿) AND PACKAGE LEAFLET; -UPDATING EXCIPIENT INFORMATION IN

										ALIGNMENT WITH EMA GUIDELINE, IMPACTING SMPC SECTION 2 (¿QUALITATIVE AND QUANTITATIVE COMPOSITION¿), SMPC SECTION 4.4 (¿SPECIAL WARNINGS AND PRECAUTIONS FOR USE¿), LABELLING AND PACKAGE LEAFLET.
PL 35728/0004	RETROVIR 100MG/10ML ORAL SOLUTION	GRANTED	PL 35728/0004-0044	PL 35728/0004-0044	07/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.9 OF THE SMPC -UPDATING ZIDOVUDINE OVERDOSAGE INFORMATION, IMPACTING SMPC SECTION 4.9 (¿OVERDOSE¿) AND PACKAGE LEAFLET; -UPDATING EXCIPIENT INFORMATION IN ALIGNMENT WITH EMA GUIDELINE, IMPACTING SMPC SECTION 2 (¿QUALITATIVE AND QUANTITATIVE COMPOSITION¿), SMPC SECTION 4.4 (¿SPECIAL WARNINGS AND PRECAUTIONS FOR USE¿),

										LABELLING AND PACKAGE LEAFLET.
PL 35728/0005	RETROVIR 10 MG/ML IV CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 35728/0005-0045	PL 35728/0005-0045	07/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.9 OF THE SMPC -UPDATING ZIDOVUDINE OVERDOSAGE INFORMATION, IMPACTING SMPC SECTION 4.9 (¿OVERDOSE¿) AND PACKAGE LEAFLET; -UPDATING EXCIPIENT INFORMATION IN ALIGNMENT WITH EMA GUIDELINE, IMPACTING SMPC SECTION 2 (¿QUALITATIVE AND QUANTITATIVE COMPOSITION¿), SMPC SECTION 4.4 (¿SPECIAL WARNINGS AND PRECAUTIONS FOR USE¿), LABELLING AND PACKAGE LEAFLET.
PL 04425/0327	IKOREL 10MG TABLETS	GRANTED	PL 04425/0327-0061	PL 04425/0327-0061	12/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC REGARDING ULCERATIONS-RELATED EVENTS BASED ON THE RESULT OF THE POST

										AUTHORISATION SAFETY STUDY (PASS). 2. TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC REGARDING OCULOMOTOR NERVE PARALYSIS DUE TO SIGNAL DETECTED IN THE LITERATURE. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04425/0327	NICORANDIL 10MG TABLETS	GRANTED	PL 04425/0327-0061	PL 04425/0327-0061	12/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC REGARDING ULCERATIONS-RELATED EVENTS BASED ON THE RESULT OF THE POST AUTHORISATION SAFETY STUDY (PASS). 2. TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC REGARDING OCULOMOTOR NERVE PARALYSIS DUE TO SIGNAL DETECTED IN THE LITERATURE. CONSEQUENTIALLY

										THE PIL HAS BEEN UPDATED.
PL 04425/0328	IKOREL 20MG TABLETS	GRANTED	PL 04425/0328-0063	PL 04425/0328-0063	12/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC REGARDING ULCERATIONS-RELATED EVENTS BASED ON THE RESULT OF THE POST AUTHORISATION SAFETY STUDY (PASS). 2. TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC REGARDING OCULOMOTOR NERVE PARALYSIS DUE TO SIGNAL DETECTED IN THE LITERATURE. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04425/0328	NICORANDIL 20MG TABLETS	GRANTED	PL 04425/0328-0063	PL 04425/0328-0063	12/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC REGARDING ULCERATIONS-RELATED EVENTS BASED ON THE RESULT OF THE POST AUTHORISATION SAFETY STUDY (PASS).

										2. TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SPC REGARDING OCULOMOTOR NERVE PARALYSIS DUE TO SIGNAL DETECTED IN THE LITERATURE. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04569/0516	SIMVASTATIN 10MG TABLETS	GRANTED	PL 04569/0516-0126	PL 04569/0516-0126	12/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC, SECTION (4.3 ONLY FOR STRENGTH 80 MG) AND PIL TEXT FOR SIMVASTATIN 10, 20, 40 AND 80 MG FILM-COATED TABLETS IN LINE WITH THE REFERENCE PRODUCT ZOCOR (AUTHORISED VIA MRP, PROCEDURE FI/H/0995). ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO LABELLING AND PIL. MOREOVER, THE PRODUCT INFORMATION HAS BEEN UPDATED IN LINE WITH THE QRD TEMPLATE (VERSION 4.1).

PL 04569/0517	SIMVASTATIN 20MG TABLETS	GRANTED	PL 04569/0517-0136	PL 04569/0517-0136	12/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC, SECTION (4.3 ONLY FOR STRENGTH 80 MG) AND PIL TEXT FOR SIMVASTATIN 10, 20, 40 AND 80 MG FILM-COATED TABLETS IN LINE WITH THE REFERENCE PRODUCT ZOCOR (AUTHORISED VIA MRP, PROCEDURE FI/H/0995). ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO LABELLING AND PIL. MOREOVER, THE PRODUCT INFORMATION HAS BEEN UPDATED IN LINE WITH THE QRD TEMPLATE (VERSION 4.1).
PL 04569/0518	SIMVASTATIN 40MG TABLETS	GRANTED	PL 04569/0518-0130	PL 04569/0518-0130	12/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC, SECTION (4.3 ONLY FOR STRENGTH 80 MG) AND PIL TEXT FOR SIMVASTATIN 10, 20, 40 AND 80 MG FILM-COATED TABLETS IN LINE WITH THE REFERENCE PRODUCT ZOCOR (AUTHORISED VIA MRP, PROCEDURE FI/H/0995).

										ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO LABELLING AND PIL. MOREOVER, THE PRODUCT INFORMATION HAS BEEN UPDATED IN LINE WITH THE QRD TEMPLATE (VERSION 4.1).
PL 04569/0519	SIMVASTATIN 80MG TABLETS	GRANTED	PL 04569/0519-0125	PL 04569/0519-0125	12/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.5 OF THE SMPC, SECTION (4.3 ONLY FOR STRENGTH 80 MG) AND PIL TEXT FOR SIMVASTATIN 10, 20, 40 AND 80 MG FILM-COATED TABLETS IN LINE WITH THE REFERENCE PRODUCT ZOCOR (AUTHORISED VIA MRP, PROCEDURE FI/H/0995). ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO LABELLING AND PIL. MOREOVER, THE PRODUCT INFORMATION HAS BEEN UPDATED IN LINE WITH THE QRD TEMPLATE (VERSION 4.1).
PL 00057/0534	LOPID 300 MG HARD CAPSULE	GRANTED	PL 00057/0	PL 00057/0	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4 AND 4.5 OF THE SMPC AND

			534-0056	534-0056				(STANDARD) - CMS		SECTION 2 OF PIL FOR LOPID 300 MG CAPSULES, HARD AND LOPID 600 MG FILM-COATED TABLETS TO ADD CONTRAINDICATION, WARNING, AND DRUG INTERACTION REGARDING THE CO-ADMINISTRATION OF GEMFIBROZIL WITH ROSUVASTATIN AT 40MG. ADDITIONALLY THE SMPC AND PIL HAS BEEN UPDATED TO ALIGN WITH COMMON SPC AND PIL.
PL 00057/0535	LOPID 600 MG FILM-COATED TABLET	GRANTED	PL 00057/0535-0043	PL 00057/0535-0043	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4 AND 4.5 OF THE SMPC AND SECTION 2 OF PIL FOR LOPID 300 MG CAPSULES, HARD AND LOPID 600 MG FILM-COATED TABLETS TO ADD CONTRAINDICATION, WARNING, AND DRUG INTERACTION REGARDING THE CO-ADMINISTRATION OF GEMFIBROZIL WITH ROSUVASTATIN AT 40MG. ADDITIONALLY THE SMPC AND PIL HAS BEEN UPDATED TO ALIGN WITH

										COMMON SPC AND PIL.
PL 00093/0022	INDAPAMIDE TABLETS 2.5MG	GRANTED	PL 00093/0022-0057	PL 00093/0022-0057	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA. 2) TO UPDATE SECTIONS 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA.
PL 00093/0022	NATRILIX 2.5MG TABLETS	GRANTED	PL 00093/0022-0057	PL 00093/0022-0057	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA. 2) TO UPDATE SECTIONS 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC

										AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA.
PL 04425/0214	FRISIUM TABLETS 10MG	GRANTED	PL 04425/0214-0077	PL 04425/0214-0077	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AS REQUESTED BY THE CMDH IN APRIL 2018 AND JUNE 2018 AND IN ORDER TO HARMONIZE APPROACH IN THE EU SMPC, SANOFI WITH CONSEQUENTIAL UPDATE TO SECTION 2 OF THE PIL.
PL 05815/0010	NATRILIX SR 1.5MG SUSTAINED RELEASE COATED TABLETS	GRANTED	PL 05815/0010-0077	PL 05815/0010-0077	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA. 2) TO UPDATE SECTIONS 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA.

PL 05815/0052	COVERSYL ARGININE PLUS 5MG/1.25MG FILM-COATED TABLETS	GRANTED	PL 05815/0052-0080	PL 05815/0052-0080	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	1) TO UPDATE SECTIONS 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA. 2) TO UPDATE SECTIONS 4.4, 4.5, 4.6 AND 4.8 OF THE SMPC AND PIL DUE TO NEW QUALITY, PRECLINICAL, CLINICAL OR PHARMACOVIGILANCE DATA.
PL 16950/0136	BUTRANS 5	GRANTED	PL 16950/0136-0059	PL 16950/0136-0059	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND PIL TO IMPLEMENT UPDATES IN CCDS V 11 (TYPE II C.I.4(X1)) AND TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS (TYPE IB C.I.Z (X1)).

PL 16950/0136	BUTRANS 5	GRANTED	PL 16950/0136-0059	PL 16950/0136-0059	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND PIL TO IMPLEMENT UPDATES IN CCDS V 11 (TYPE II C.I.4(X1)) AND TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS (TYPE IB C.I.Z (X1)).
PL 16950/0137	BUTRANS 10	GRANTED	PL 16950/0137-0058	PL 16950/0137-0058	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND PIL TO IMPLEMENT UPDATES IN CCDS V 11 (TYPE II C.I.4(X1)) AND TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS (TYPE IB C.I.Z (X1)).
PL 16950/0137	BUTRANS 10	GRANTED	PL 16950/0137-0058	PL 16950/0137-0058	14/04/2021	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 AND 5.1 OF THE SMPC AND PIL TO IMPLEMENT UPDATES IN CCDS V 11 (TYPE II C.I.4(X1)) AND TO

								GROUPING		IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS (TYPE IB C.I.Z (X1)).
PL 16950/0138	BUTRANS 20	GRANTED	PL 16950/0138-0058	PL 16950/0138-0058	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND PIL TO IMPLEMENT UPDATES IN CCDS V 11 (TYPE II C.I.4(X1)) AND TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS (TYPE IB C.I.Z (X1)).
PL 16950/0138	BUTRANS 20	GRANTED	PL 16950/0138-0058	PL 16950/0138-0058	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND PIL TO IMPLEMENT UPDATES IN CCDS V 11 (TYPE II C.I.4(X1)) AND TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND

										OPIOIDS (TYPE IB C.I.Z (X1)).
PL 16950/0349	BUTRANS 15 MICROGRAM/HOUR	GRANTED	PL 16950/0349-0024	PL 16950/0349-0024	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND PIL TO IMPLEMENT UPDATES IN CCDS V 11 (TYPE II C.I.4(X1)) AND TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS (TYPE IB C.I.Z (X1)).
PL 16950/0349	BUTRANS 15 MICROGRAM/HOUR	GRANTED	PL 16950/0349-0024	PL 16950/0349-0024	14/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 4.6, 4.8, 4.9 AND 5.1 OF THE SMPC AND PIL TO IMPLEMENT UPDATES IN CCDS V 11 (TYPE II C.I.4(X1)) AND TO IMPLEMENT CMDH WORDING REGARDING THE CONCOMITANT USE OF BENZODIAZEPINES/BENZODIAZEPINE LIKE PRODUCTS AND OPIOIDS (TYPE IB C.I.Z (X1)).
PL 04416/1164	ALENDRONIC ACID AND CALCIUM/CHOLECALCIFEROL	GRANTED	PL 04416/1164-0039	PL 04416/1164-0039	21/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTION 2, 4.2, 4.4, 4.7, 4.8, 4.9, 5.1, 5.2, 6.5 OF THE SMPC AND THE PIL

	70MG+1000MG/880 IU FILM-COATED TABLETS+ EFFERVESCENT TAB							RD) - RMS		FOR MINOR EDITORIAL AND FORMAT CHANGES HAVE BEEN IMPLEMENTED TO IMPROVE THE TEXTS.
PL 04425/0757	BUSCOMINT PEPPERMINT OIL 0.2ML GASTRO-RESISTANT CAPSULE, SOFT	GRANTED	PL 04425/0757-0009	PL 04425/0757-0009	27/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE THE RISK MANAGEMENT PLAN IN ACCORDANCE WITH GVP MODULE V, REVISION 2.
PL 16950/0042	MXL 30MG PROLONGED RELEASE CAPSULES	GRANTED	PL 16950/0042-0072	PL 16950/0042-0072	27/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) FOR OPIOID PRODUCTS, INCLUDING THE MORPHINE SULFATE CCDS: · SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND · SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.

										2) TO UPDATE SECTIONS 4.3, 4.5 AND 4.6 OF THE SMPC AND PIL TO HARMONIZE WITH OUR PROCEDURAL TEXTS AFTER THE OPIODAL PRODUCTS CCDS REVIEW.
PL 16950/0042	MXL 30MG PROLONGED RELEASE CAPSULES	GRANTED	PL 16950/0042-0072	PL 16950/0042-0072	27/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) FOR OPIOID PRODUCTS, INCLUDING THE MORPHINE SULFATE CCDS: · SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND · SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.

										2) TO UPDATE SECTIONS 4.3, 4.5 AND 4.6 OF THE SMPC AND PIL TO HARMONIZE WITH OUR PROCEDURAL TEXTS AFTER THE OPIODAL PRODUCTS CCDS REVIEW.
PL 16950/0043	MXL 60MG PROLONGED RELEASE CAPSULES	GRANTED	PL 16950/0043-0071	PL 16950/0043-0071	27/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) FOR OPIOID PRODUCTS, INCLUDING THE MORPHINE SULFATE CCDS: · SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND · SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.

										2) TO UPDATE SECTIONS 4.3, 4.5 AND 4.6 OF THE SMPC AND PIL TO HARMONIZE WITH OUR PROCEDURAL TEXTS AFTER THE OPIODAL PRODUCTS CCDS REVIEW.
PL 16950/0043	MXL 60MG PROLONGED RELEASE CAPSULES	GRANTED	PL 16950/0043-0071	PL 16950/0043-0071	27/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) FOR OPIOID PRODUCTS, INCLUDING THE MORPHINE SULFATE CCDS: · SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND · SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.

										2) TO UPDATE SECTIONS 4.3, 4.5 AND 4.6 OF THE SMPC AND PIL TO HARMONIZE WITH OUR PROCEDURAL TEXTS AFTER THE OPIODAL PRODUCTS CCDS REVIEW.
PL 16950/0045	MXL 120MG PROLONGED RELEASE CAPSULES	GRANTED	PL 16950/0045-0071	PL 16950/0045-0071	27/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) FOR OPIOID PRODUCTS, INCLUDING THE MORPHINE SULFATE CCDS: · SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND · SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.

										2) TO UPDATE SECTIONS 4.3, 4.5 AND 4.6 OF THE SMPC AND PIL TO HARMONIZE WITH OUR PROCEDURAL TEXTS AFTER THE OPIODAL PRODUCTS CCDS REVIEW.
PL 16950/0045	MXL 120MG PROLONGED RELEASE CAPSULES	GRANTED	PL 16950/0045-0071	PL 16950/0045-0071	27/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) FOR OPIOID PRODUCTS, INCLUDING THE MORPHINE SULFATE CCDS: · SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND · SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.

										2) TO UPDATE SECTIONS 4.3, 4.5 AND 4.6 OF THE SMPC AND PIL TO HARMONIZE WITH OUR PROCEDURAL TEXTS AFTER THE OPIODAL PRODUCTS CCDS REVIEW.
PL 16950/0047	MXL 200MG PROLONGED RELEASE CAPSULES	GRANTED	PL 16950/0047-0074	PL 16950/0047-0074	27/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) FOR OPIOID PRODUCTS, INCLUDING THE MORPHINE SULFATE CCDS: · SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND · SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.

										2) TO UPDATE SECTIONS 4.3, 4.5 AND 4.6 OF THE SMPC AND PIL TO HARMONIZE WITH OUR PROCEDURAL TEXTS AFTER THE OPIODAL PRODUCTS CCDS REVIEW.
PL 16950/0047	MXL 200MG PROLONGED RELEASE CAPSULES	GRANTED	PL 16950/0047-0074	PL 16950/0047-0074	27/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1) TO UPDATE THE COMPANY CORE DATA SHEETS (CCDS) FOR OPIOID PRODUCTS, INCLUDING THE MORPHINE SULFATE CCDS: · SECTION 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE SHOULD BE UPDATED WITH A WARNING REGARDING THE RELATIONSHIP BETWEEN OPIOIDS AND SLEEP APNOEA, SPECIFICALLY CENTRAL SLEEP APNOEA; AND · SECTION 4.8 UNDESIRABLE EFFECTS SHOULD BE UPDATED TO LIST SLEEP APNOEA SYNDROME.

										2) TO UPDATE SECTIONS 4.3, 4.5 AND 4.6 OF THE SMPC AND PIL TO HARMONIZE WITH OUR PROCEDURAL TEXTS AFTER THE OPIODAL PRODUCTS CCDS REVIEW.
PL 12308/0010	XENETIX 300 (300 MGI/ML) SOLUTION FOR INJECTION)	GRANTED	PL 12308/0010-0111	PL 12308/0010-0111	28/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.1, 4.2, 4.3, 4.4, 4.8 AND 5.1 OF THE SMPC AND PIL FOLLOWING THE PSUSA/00001761/201904 FOR XENETIX (IOBITRIDOL), COVERING THE PERIOD FROM MAY 1ST, 2014 TO APRIL 30TH 2019. *MA FOR 250MG HAS BEEN CANCELLED. 300MG AND 350MG STRENGTHS ARE NOT CURRENTLY MARKETED, THEREFORE, ONLY PIL TEXT HAS BEEN SUBMITTED.
PL 12308/0011	XENETIX 350 (350 MGI/ML) SOLUTION FOR INJECTION)	GRANTED	PL 12308/0011-0107	PL 12308/0011-0107	28/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 2, 3, 4.1, 4.2, 4.3, 4.4, 4.8 AND 5.1 OF THE SMPC AND PIL FOLLOWING THE PSUSA/00001761/20190

								WORKSHARING		4 FOR XENETIX (IOBITRIDOL), COVERING THE PERIOD FROM MAY 1ST, 2014 TO APRIL 30TH 2019. *MA FOR 250MG HAS BEEN CANCELLED. 300MG AND 350MG STRENGTHS ARE NOT CURRENTLY MARKETED, THEREFORE, ONLY PIL TEXT HAS BEEN SUBMITTED.
PL 52497/0001	MELATONIN AGB 1MG TABLET	GRANTED	PL 52497/0001-0002	PL 52497/0001-0002	29/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE A POST-AUTHORISATION SAFETY STUDY (PASS) IN ORDER TO MEET THE CONDITIONS OF THE REGULATORY COMMITMENT TO CONDUCT SUCH A PASS STUDY (CATEGORY 3) ON LONG-TERM SAFETY IN PREPUBERTAL AND PUBERTAL CHILDREN.
PL 52497/0002	MELATONIN AGB 2MG TABLET	GRANTED	PL 52497/0002-0002	PL 52497/0002-0002	29/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE A POST-AUTHORISATION SAFETY STUDY (PASS) IN ORDER TO MEET THE CONDITIONS OF THE REGULATORY COMMITMENT TO CONDUCT SUCH A PASS STUDY (CATEGORY 3) ON

										LONG-TERM SAFETY IN PREPUBERTAL AND PUBERTAL CHILDREN.
PL 52497/0003	MELATONIN AGB 3MG TABLET	GRANTED	PL 52497/0003-0002	PL 52497/0003-0002	29/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE A POST-AUTHORISATION SAFETY STUDY (PASS) IN ORDER TO MEET THE CONDITIONS OF THE REGULATORY COMMITMENT TO CONDUCT SUCH A PASS STUDY (CATEGORY 3) ON LONG-TERM SAFETY IN PREPUBERTAL AND PUBERTAL CHILDREN.
PL 52497/0004	MELATONIN AGB 4MG TABLET	GRANTED	PL 52497/0004-0002	PL 52497/0004-0002	29/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE A POST-AUTHORISATION SAFETY STUDY (PASS) IN ORDER TO MEET THE CONDITIONS OF THE REGULATORY COMMITMENT TO CONDUCT SUCH A PASS STUDY (CATEGORY 3) ON LONG-TERM SAFETY IN PREPUBERTAL AND PUBERTAL CHILDREN.
PL 52497/0005	MELATONIN AGB 5MG TABLET	GRANTED	PL 52497/0005-0002	PL 52497/0005-0002	29/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO INTRODUCE A POST-AUTHORISATION SAFETY STUDY (PASS) IN ORDER TO MEET THE CONDITIONS OF THE REGULATORY COMMITMENT TO CONDUCT SUCH A PASS STUDY (CATEGORY 3) ON

										LONG-TERM SAFETY IN PREPUBERTAL AND PUBERTAL CHILDREN.
PL 00010/0519	ANDROCUR 50MG TABLETS	GRANTED	PL 00010/0519-0054	PL 00010/0519-0054	30/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE A PROTOCOL FOR A POST-AUTHORISATION SAFETY STUDY (PASS) WHOSE CONDUCT HAS BEEN REQUESTED WITH CONCLUSION OF THE ARTICLE 31 REFERRAL EMEA/H/A-31/1488 ON MEDICINAL PRODUCTS CONTAINING CYPROTERONE ACETATE (CPA). AS RECOMMENDED BY PRAC AND FINALLY ENDORSED BY CMDH A PASS IS REQUESTED TO EVALUATE THE PHYSICIANS' AWARENESS AND LEVEL OF KNOWLEDGE OF THE INFORMATION INCLUDED IN THE SMPC AND DHPC REGARDING RISK OF MENINGIOMA BEING DISTRIBUTED EARLIER THIS YEAR AFTER COMPLETION OF THE REFERRAL.

PL 00010/0524	CYPROSTAT 100MG TABLETS	GRANTED	PL 00010/0524-0051	PL 00010/0524-0051	30/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE A PROTOCOL FOR A POST-AUTHORISATION SAFETY STUDY (PASS) WHOSE CONDUCT HAS BEEN REQUESTED WITH CONCLUSION OF THE ARTICLE 31 REFERRAL EMEA/H/A-31/1488 ON MEDICINAL PRODUCTS CONTAINING CYPROTERONE ACETATE (CPA). AS RECOMMENDED BY PRAC AND FINALLY ENDORSED BY CMDH A PASS IS REQUESTED TO EVALUATE THE PHYSICIANS' AWARENESS AND LEVEL OF KNOWLEDGE OF THE INFORMATION INCLUDED IN THE SMPC AND DHPC REGARDING RISK OF MENINGIOMA BEING DISTRIBUTED EARLIER THIS YEAR AFTER COMPLETION OF THE REFERRAL.
PL 00010/0525	CYPROSTAT 50MG TABLETS	GRANTED	PL 00010/0525-0060	PL 00010/0525-0060	30/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	TO INTRODUCE A PROTOCOL FOR A POST-AUTHORISATION SAFETY STUDY (PASS) WHOSE CONDUCT

								CMS WORKSHARING		HAS BEEN REQUESTED WITH CONCLUSION OF THE ARTICLE 31 REFERRAL EMEA/H/A-31/1488 ON MEDICINAL PRODUCTS CONTAINING CYPROTERONE ACETATE (CPA). AS RECOMMENDED BY PRAC AND FINALLY ENDORSED BY CMDH A PASS IS REQUESTED TO EVALUATE THE PHYSICIANS' AWARENESS AND LEVEL OF KNOWLEDGE OF THE INFORMATION INCLUDED IN THE SMPC AND DHPC REGARDING RISK OF MENINGIOMA BEING DISTRIBUTED EARLIER THIS YEAR AFTER COMPLETION OF THE REFERRAL.
PL 04569/0278	CYPROTERONE ACETATE TABLETS 50MG	GRANTED	PL 04569/0278-0059	PL 04569/0278-0059	30/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE A PROTOCOL FOR A POST-AUTHORISATION SAFETY STUDY (PASS) WHOSE CONDUCT HAS BEEN REQUESTED WITH CONCLUSION OF THE ARTICLE 31 REFERRAL EMEA/H/A-31/1488 ON

										MEDICINAL PRODUCTS CONTAINING CYPROTERONE ACETATE (CPA). AS RECOMMENDED BY PRAC AND FINALLY ENDORSED BY CMDH A PASS IS REQUESTED TO EVALUATE THE PHYSICIANS' AWARENESS AND LEVEL OF KNOWLEDGE OF THE INFORMATION INCLUDED IN THE SMPC AND DHPC REGARDING RISK OF MENINGIOMA BEING DISTRIBUTED EARLIER THIS YEAR AFTER COMPLETION OF THE REFERRAL.
PL 21844/0001	CYPROTERONE ACETATE 50MG TABLETS	GRANTED	PL 21844/0001-0036	PL 21844/0001-0036	30/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE A PROTOCOL FOR A POST-AUTHORISATION SAFETY STUDY (PASS) WHOSE CONDUCT HAS BEEN REQUESTED WITH CONCLUSION OF THE ARTICLE 31 REFERRAL EMEA/H/A-31/1488 ON MEDICINAL PRODUCTS CONTAINING CYPROTERONE ACETATE (CPA). AS

										RECOMMENDED BY PRAC AND FINALLY ENDORSED BY CMDH A PASS IS REQUESTED TO EVALUATE THE PHYSICIANS' AWARENESS AND LEVEL OF KNOWLEDGE OF THE INFORMATION INCLUDED IN THE SMPC AND DHPC REGARDING RISK OF MENINGIOMA BEING DISTRIBUTED EARLIER THIS YEAR AFTER COMPLETION OF THE REFERRAL.
PL 21844/0002	CYPROTERONE ACETATE 100MG TABLETS	GRANTED	PL 21844/0002-0026	PL 21844/0002-0026	30/04/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO INTRODUCE A PROTOCOL FOR A POST-AUTHORISATION SAFETY STUDY (PASS) WHOSE CONDUCT HAS BEEN REQUESTED WITH CONCLUSION OF THE ARTICLE 31 REFERRAL EMEA/H/A-31/1488 ON MEDICINAL PRODUCTS CONTAINING CYPROTERONE ACETATE (CPA). AS RECOMMENDED BY PRAC AND FINALLY ENDORSED BY CMDH A PASS IS REQUESTED TO

										EVALUATE THE PHYSICIANS' AWARENESS AND LEVEL OF KNOWLEDGE OF THE INFORMATION INCLUDED IN THE SMPC AND DHPC REGARDING RISK OF MENINGIOMA BEING DISTRIBUTED EARLIER THIS YEAR AFTER COMPLETION OF THE REFERRAL.
PL 04515/0227	IRINOTECAN HYDROCHLORIDE 20MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 04515/0227-0066	PL 04515/0227-0066	04/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 2, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.2, 6.3, 6.4 AND 6.6 OF THE SMPC IN LINE WITH THE REFERENCE PRODUCT, CAMPTO 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION (PL 00057/0626 - MAH: PFIZER LIMITED). ADDITIONAL MINOR EDITORIAL CHANGES HAVE BEEN MADE IN LINE WITH THE CURRENT QRD TEMPLATE. FURTHERMORE, UPDATES HAVE BEEN MADE TO ALIGN WITH THE CURRENT

										GUIDELINE ON EXCIPIENTS IN THE LABEL AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE. CONSEQUENTLY, THE PIL AND PACKAGE LABELLING HAVE BEEN UPDATED.
PL 20075/1382	CISATRACURIUM 5 MG/ML SOLUTION FOR INJECTION/INFUSION	GRANTED	PL 20075/1382-0002	PL 20075/1382-0002	11/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 2, 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 5.1, 5.2, 5.3, 6.3, 6.5 AND 7 OF THE SMPC AS A RESULT OF COMMENTS RECEIVED FROM THE NEW CMS DURING A REPEAT USE PROCEDURE (RUP). CONSEQUENTLY, THE PIL AND PACKAGE LABELLING HAVE BEEN UPDATED.
PL 17770/0001	ZIBOR 2,500 IU ANTI-XA/0.2 ML SOLUTION FOR INJECTION	GRANTED	PL 17770/0001-0048	PL 17770/0001-0048	12/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SIGNAL ¿HEMORRHAGIC ANEMIA¿, AS A NEW ADVERSE REACTION, IN SECTION 4.8 (ADVERSE REACTIONS) OF THE PHIVOR (ZIBOR, IVOR) SMPC.

PL 17770/0002	ZIBOR 3,500 IU ANTI-XA/0.2ML SOLUTION FOR INJECTION	GRANTED	PL 17770/0002-0049	PL 17770/0002-0049	12/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SIGNAL ¿HEMORRHAGIC ANEMIA¿, AS A NEW ADVERSE REACTION, IN SECTION 4.8 (ADVERSE REACTIONS) OF THE PHIVOR (ZIBOR, IVOR) SMPC.
PL 17770/0003	ZIBOR 25,000 IU ANTI-XA/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGES	GRANTED	PL 17770/0003-0044	PL 17770/0003-0044	12/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS	MUTUAL RECOGNITION	TO UPDATE THE SIGNAL ¿HEMORRHAGIC ANEMIA¿, AS A NEW ADVERSE REACTION, IN SECTION 4.8 (ADVERSE REACTIONS) OF THE PHIVOR (ZIBOR, IVOR) SMPC.
PL 20011/0072	ANGUSTA 25 MICROGRAM TABLETS	GRANTED	PL 20011/0072-0006	PL 20011/0072-0006	19/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN TO INCLUDE FULL REASSESSMENT OF THE SAFETY CONCERNS AND THE NEED FOR ADDITIONAL RISK MINIMISATION MEASURES (E.G. A DHPC) FOLLOWING APPROVAL OF THE REPEAT USE PROCEDURE (RUP) DK/H/2584/001/E/002. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 00242/0192	DUROGESIC DTRANS 25 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0192-0158	PL 00242/0192-0158	25/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, AND 4.8 OF THE SPC OF DUROGESIC DUE TO NEW QUALITY, PRECLINICAL, CLINICAL AND PHARMACOVIGILANCE DATA.
PL 00242/0192	DUROGESIC DTRANS 25 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0192-0160	PL 00242/0192-0160	25/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND PATIENT INFORMATION LEAFLET TO ADD WARNING TEXT REGARDING OPIOID INDUCED HYPERALGESIA. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SECTION 4.1, 4.4 AND 4.8 OF THE SMPC AND PIL.
PL 00242/0193	DUROGESIC DTRANS 50 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0193-0156	PL 00242/0193-0156	25/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, AND 4.8 OF THE SPC OF DUROGESIC DUE TO NEW QUALITY, PRECLINICAL, CLINICAL AND PHARMACOVIGILANCE DATA.
PL 00242/0193	DUROGESIC DTRANS 50 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0193-0158	PL 00242/0193-0158	25/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND PATIENT INFORMATION LEAFLET TO ADD WARNING TEXT

										REGARDING OPIOID INDUCED HYPERALGESIA. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SECTION 4.1, 4.4 AND 4.8 OF THE SMPC AND PIL.
PL 00242/0194	DUROGESIC DTRANS 75 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0194-0154	PL 00242/0194-0154	25/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, AND 4.8 OF THE SPC OF DUROGESIC DUE TO NEW QUALITY, PRECLINICAL, CLINICAL AND PHARMACOVIGILANCE DATA.
PL 00242/0194	DUROGESIC DTRANS 75 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0194-0156	PL 00242/0194-0156	25/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND PATIENT INFORMATION LEAFLET TO ADD WARNING TEXT REGARDING OPIOID INDUCED HYPERALGESIA. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SECTION 4.1, 4.4 AND 4.8 OF THE SMPC AND PIL.
PL 00242/0195	DUROGESIC DTRANS 100 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0195-0155	PL 00242/0195-0155	25/05/2021	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 SPC OF DUROGESIC DUE TO NEW QUALITY, PRECLINICAL,

								GROUPING		CLINICAL AND PHARMACOVIGILANCE DATA.
PL 00242/0195	DUROGESIC DTRANS 100 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0195-0157	PL 00242/0195-0157	25/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND PATIENT INFORMATION LEAFLET TO ADD WARNING TEXT REGARDING OPIOID INDUCED HYPERALGESIA. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO SECTION 4.1, 4.4 AND 4.8 OF THE SMPC AND PIL.
PL 00242/0409	DUROGESIC DTRANS 12 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0409-0100	PL 00242/0409-0100	25/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.4, 4.5, AND 4.8 OF THE SPC OF DUROGESIC DUE TO NEW QUALITY, PRECLINICAL, CLINICAL AND PHARMACOVIGILANCE DATA.
PL 00242/0409	DUROGESIC DTRANS 12 MCG/HR TRANSDERMAL PATCH	GRANTED	PL 00242/0409-0102	PL 00242/0409-0102	25/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC AND PATIENT INFORMATION LEAFLET TO ADD WARNING TEXT REGARDING OPIOID INDUCED HYPERALGESIA. ADDITIONALLY SOME EDITORIAL CHANGES HAS BEEN MADE TO

										SECTION 4.1, 4.4 AND 4.8 OF THE SMPC AND PIL.
PL 10921/0023	COPAXONE 20MG/ML SOLUTION FOR INJECTION, PREFILLED SYRINGE	GRANTED	PL 10921/0023-0214	PL 10921/0023-0214	27/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AS PART OF POST APPROVAL COMMITMENT (PAC) ON THE RISK OF DRUG INDUCED LIVER INJURY (DILI) CASES.
PL 10921/0026	COPAXONE 40 MG/ML SOLUTION FOR INJECTION, PRE-FILLED SYRINGE	GRANTED	PL 10921/0026-0046	PL 10921/0026-0046	27/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AS PART OF POST APPROVAL COMMITMENT (PAC) ON THE RISK OF DRUG INDUCED LIVER INJURY (DILI) CASES.
PL 20075/1381	ABACAVIR ACCORD 300 MG FILM-COATED TABLETS	GRANTED	PL 20075/1381-0004	PL 20075/1381-0004	28/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE IB - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.4, 5.1 AND 6.1 OF THE SMPC FRAGMENTS AS PER THE COMMITMENT PROVIDED BY MAH DURING RUP NL/H/3482/001/E/001. SECTION 4.4 HAS BEEN UPDATED FOR THE EXCIPIENT WARNING FOR SODIUM. SECTION 5.1 HAS BEEN UPDATED TO INCLUDE THE MISSING WEEK NUMBER IN THE LAST TABLE.

										SECTION 6.1 HAS BEEN UPDATED TO REMOVE THE E NUMBER FOR EXCIPIENTS WHICH ARE NOT EXCIPIENTS OF KNOWN EFFECT. CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 00057/1517	MENINGOCOCCAL GROUP C POLYSACCHARIDE CONJUGATE VACCINE ADSORBED	GRANTED	PL 00057/1517-0034	PL 00057/1517-0034	30/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SPC AND PACKAGE LEAFLET TO COMPLY WITH THE REQUIREMENTS OF THE QUALITY REVIEW OF DOCUMENTS (QRD VERSION 10), TO CONFORM TO PFIZER FORMATTING STANDARDS, AND TO MAKE ADDITIONAL REVISIONS TO THE TEXT TO REFLECT CURRENT VACCINATION PRACTICES AND TO IMPROVE READABILITY AND COMPREHENSION.
PL 00057/1517	NEISVAC-C 0.5 ML SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 00057/1517-0034	PL 00057/1517-0034	30/05/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SPC AND PACKAGE LEAFLET TO COMPLY WITH THE REQUIREMENTS OF THE QUALITY REVIEW OF DOCUMENTS (QRD

										VERSION 10), TO CONFORM TO PFIZER FORMATTING STANDARDS, AND TO MAKE ADDITIONAL REVISIONS TO THE TEXT TO REFLECT CURRENT VACCINATION PRACTICES AND TO IMPROVE READABILITY AND COMPREHENSION.
PL 06958/0031	AZZALURE, 125 SPEYWOOD UNITS, POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 06958/0031-0087	PL 06958/0031-0087	01/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	1) TO UPDATE SECTION 4.4 OF THE SPC TO REPLACE THE SENTENCE `THE EFFECT OF ADMINISTERING DIFFERENT BOTULINUM NEUROTOXINS DURING THE COURSE OF TREATMENT WITH AZZALURE IS UNKNOWN AND MUST BE AVOIDED' WITH `BOTULINUM TOXIN UNITS ARE NOT INTERCHANGEABLE FROM ONE PRODUCT TO ANOTHER. DOSES RECOMMENDED IN SPEYWOOD UNITS ARE DIFFERENT FROM OTHER BOTULINUM TOXIN PREPARATIONS.'

										2) TO UPDATE SECTION 4.4 OF THE SPC TO INCLUDE A WARNING ABOUT `DRY EYE'.  3) TO UPDATE SECTION 4.8 OF THE SPC TO INCLUDE THE ADR `HYPERSENSITIVITY' WITH FREQUENCY UNKNOWN TO THE POST MARKETING EXPERIENCE PARAGRAPH. 4) TO UPDATE SECTION 4.8 OF THE SPC TO INCLUDE THE ADR `MUSCLE ATROPHY' WITH FREQUENCY UNKNOWN TO THE POST MARKETING EXPERIENCE PARAGRAPH. 5) TO UPDATE SECTIONS 4.4 AND 6.6 OF THE SPC IN LINE WITH THE QRD TEMPLATE. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 06958/0031	AZZALURE, 125 SPEYWOOD UNITS, POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 06958/0031-0087	PL 06958/0031-0087	01/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	1) TO UPDATE SECTION 4.4 OF THE SPC TO REPLACE THE SENTENCE `THE EFFECT OF ADMINISTERING DIFFERENT BOTULINUM NEUROTOXINS DURING THE COURSE OF TREATMENT WITH AZZALURE IS UNKNOWN AND MUST BE AVOIDED' WITH `BOTULINUM TOXIN UNITS ARE NOT INTERCHANGEABLE FROM ONE PRODUCT TO ANOTHER. DOSES RECOMMENDED IN SPEYWOOD UNITS ARE DIFFERENT FROM OTHER BOTULINUM TOXIN PREPARATIONS.' 2) TO UPDATE SECTION 4.4 OF THE SPC TO INCLUDE A WARNING ABOUT `DRY EYE'.  3) TO UPDATE SECTION 4.8 OF THE SPC TO INCLUDE THE ADR `HYPERSENSITIVITY' WITH FREQUENCY UNKNOWN TO THE

										POST MARKETING EXPERIENCE PARAGRAPH. 4) TO UPDATE SECTION 4.8 OF THE SPC TO INCLUDE THE ADR `MUSCLE ATROPHY' WITH FREQUENCY UNKNOWN TO THE POST MARKETING EXPERIENCE PARAGRAPH. 5) TO UPDATE SECTIONS 4.4 AND 6.6 OF THE SPC IN LINE WITH THE QRD TEMPLATE. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 21727/0032	PALEXIA 50 MG FILM-COATED TABLETS	GRANTED	PL 21727/0032-0059	PL 21727/0032-0059	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL FOR PALEXIA FILM COATED TABLETS, PROLONGED RELEASE TABLET AND ORAL SOLUTION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS).
PL 21727/0033	PALEXIA 75 MG FILM-COATED TABLETS	GRANTED	PL 21727/0	PL 21727/0	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II	DECENTRALISED	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL FOR PALEXIA FILM

			033-0059	033-0059				(STANDARD) - CMS		COATED TABLETS, PROLONGED RELEASE TABLET AND ORAL SOLUTION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS).
PL 21727/0041	PALEXIA SR 50 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0041-0063	PL 21727/0041-0063	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL FOR PALEXIA FILM COATED TABLETS, PROLONGED RELEASE TABLET AND ORAL SOLUTION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS).
PL 21727/0042	PALEXIA SR 100 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0042-0063	PL 21727/0042-0063	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL FOR PALEXIA FILM COATED TABLETS, PROLONGED RELEASE TABLET AND ORAL SOLUTION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS).
PL 21727/0043	PALEXIA SR 150 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0043-0063	PL 21727/0043-0063	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL FOR PALEXIA FILM COATED TABLETS, PROLONGED RELEASE TABLET AND ORAL

										SOLUTION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS).
PL 21727/0044	PALEXIA SR 200 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0044-0062	PL 21727/0044-0062	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL FOR PALEXIA FILM COATED TABLETS, PROLONGED RELEASE TABLET AND ORAL SOLUTION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS).
PL 21727/0045	PALEXIA SR 250 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0045-0064	PL 21727/0045-0064	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL FOR PALEXIA FILM COATED TABLETS, PROLONGED RELEASE TABLET AND ORAL SOLUTION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS).
PL 21727/0051	PALEXIA SR 25 MG PROLONGED-RELEASE TABLETS	GRANTED	PL 21727/0051-0055	PL 21727/0051-0055	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL FOR PALEXIA FILM COATED TABLETS, PROLONGED RELEASE TABLET AND ORAL SOLUTION TO IMPLEMENT THE ADDITION OF

										NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS).
PL 21727/0053	PALEXIA 4MG/ML ORAL SOLUTION	GRANTED	PL 21727/0053-0046	PL 21727/0053-0046	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL FOR PALEXIA FILM COATED TABLETS, PROLONGED RELEASE TABLET AND ORAL SOLUTION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS).
PL 21727/0054	PALEXIA 20MG/ML ORAL SOLUTION	GRANTED	PL 21727/0054-0048	PL 21727/0054-0048	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.6 OF THE SMPC AND PIL FOR PALEXIA FILM COATED TABLETS, PROLONGED RELEASE TABLET AND ORAL SOLUTION TO IMPLEMENT THE ADDITION OF NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS).
PL 50622/0046	NEURONTIN 100MG HARD CAPSULES	GRANTED	PL 50622/0046-0007	PL 50622/0046-0007	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	IMPLEMENTATION OF CHANGE(S) WHICH REQUIRE TO BE FURTHER SUBSTANTIATED BY NEW ADDITIONAL DATA TO BE SUBMITTED BY THE MAH IN RESPONSE TO QUESTION 1. OF THE PRAC ASSESSMENT REPORT (AR) TO THE

										MOST RECENT 2019 PERIODIC SAFETY UPDATE REPORT (PSUR) - PSUSA/00001499/201902 CONCERNING SUICIDAL RISK A SUPPORTING CLINICAL OVERVIEW (CO) IS PROVIDED IN MODULE 2.5.
PL 50622/0047	NEURONTIN 300MG HARD CAPSULES	GRANTED	PL 50622/0047-0007	PL 50622/0047-0007	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	IMPLEMENTATION OF CHANGE(S) WHICH REQUIRE TO BE FURTHER SUBSTANTIATED BY NEW ADDITIONAL DATA TO BE SUBMITTED BY THE MAH IN RESPONSE TO QUESTION 1. OF THE PRAC ASSESSMENT REPORT (AR) TO THE MOST RECENT 2019 PERIODIC SAFETY UPDATE REPORT (PSUR) - PSUSA/00001499/201902 CONCERNING SUICIDAL RISK A SUPPORTING CLINICAL OVERVIEW (CO) IS PROVIDED IN MODULE 2.5.
PL 50622/0048	NEURONTIN 400MG HARD CAPSULES	GRANTED	PL 50622/0048-0007	PL 50622/0048-0007	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) -	MUTUAL RECOGNITION	IMPLEMENTATION OF CHANGE(S) WHICH REQUIRE TO BE FURTHER SUBSTANTIATED BY

								CMS WORKSHARING		NEW ADDITIONAL DATA TO BE SUBMITTED BY THE MAH IN RESPONSE TO QUESTION 1. OF THE PRAC ASSESSMENT REPORT (AR) TO THE MOST RECENT 2019 PERIODIC SAFETY UPDATE REPORT (PSUR) - PSUSA/00001499/201902 CONCERNING SUICIDAL RISK A SUPPORTING CLINICAL OVERVIEW (CO) IS PROVIDED IN MODULE 2.5.
PL 50622/0049	NEURONTIN 600MG FILM-COATED TABLETS	GRANTED	PL 50622/0049-0007	PL 50622/0049-0007	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	IMPLEMENTATION OF CHANGE(S) WHICH REQUIRE TO BE FURTHER SUBSTANTIATED BY NEW ADDITIONAL DATA TO BE SUBMITTED BY THE MAH IN RESPONSE TO QUESTION 1. OF THE PRAC ASSESSMENT REPORT (AR) TO THE MOST RECENT 2019 PERIODIC SAFETY UPDATE REPORT (PSUR) - PSUSA/00001499/201902 CONCERNING SUICIDAL RISK A SUPPORTING CLINICAL OVERVIEW

										(CO) IS PROVIDED IN MODULE 2.5.
PL 50622/0050	NEURONTIN 800MG FILM-COATED TABLETS	GRANTED	PL 50622/0050-0007	PL 50622/0050-0007	07/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	IMPLEMENTATION OF CHANGE(S) WHICH REQUIRE TO BE FURTHER SUBSTANTIATED BY NEW ADDITIONAL DATA TO BE SUBMITTED BY THE MAH IN RESPONSE TO QUESTION 1. OF THE PRAC ASSESSMENT REPORT (AR) TO THE MOST RECENT 2019 PERIODIC SAFETY UPDATE REPORT (PSUR) - PSUSA/00001499/201902 CONCERNING SUICIDAL RISK A SUPPORTING CLINICAL OVERVIEW (CO) IS PROVIDED IN MODULE 2.5.
PL 20162/0011	MYDRIASERT 0.28 MG/5.4 MG OPHTHALMIC INSERT	GRANTED	PL 20162/0011-0046	PL 20162/0011-0046	08/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC WITH THE SIDE EFFECT 'CONVULSIONS' WITH FREQUENCY 'VERY RARE'. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 08828/0208	LEVOFLOXACIN KABI 5 MG/ML SOLUTION FOR INFUSION	GRANTED	PL 08828/0	PL 08828/0	10/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II	DECENTRALISED	TO INTRODUCE THE RISK MANAGEMENT

			208-0035	208-0035				(STANDARD) - CMS		PLAN FOR THE FINISHED PRODUCT.
PL 21039/0026	LUBION 25 MG SOLUTION FOR INJECTION	GRANTED	PL 21039/0026-0033	PL 21039/0026-0033	10/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.2 AND 4.4 OF THE SPC ACCORDING TO THE REQUESTS RAISED DURING THE SECOND-WAVE (RUP) PROCEDURE AND TO BRING IN LINE WITH THE GUIDELINE `EXCIPIENTS IN THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE¿. CONSEQUENTIALLY, THE PIL AND LABEL TEXT HAVE BEEN UPDATED.
PL 31750/0150	MIDAZOLAM 1 MG/ML SOLUTION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	GRANTED	PL 31750/0150-0006	PL 31750/0150-0006	10/06/2021	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, 4.9, 5.1 AND 5.2 OF THE SMPC FRAGMENTS IN LINE WITH CURRENT SCIENTIFIC KNOWLEDGE FOLLOWING ASSESSMENT OF THE SAME CHANGE FOR THE REFERENCE PRODUCT HYPNOVEL. CONSEQUENTIALLY

										THE PIL AND LABEL HAVE BEEN UPDATED.
PL 31750/0151	MIDAZOLAM 2 MG/ML SOLUTION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	GRANTED	PL 31750/0151-0006	PL 31750/0151-0006	10/06/2021	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, 4.9, 5.1 AND 5.2 OF THE SMPC FRAGMENTS IN LINE WITH CURRENT SCIENTIFIC KNOWLEDGE FOLLOWING ASSESSMENT OF THE SAME CHANGE FOR THE REFERENCE PRODUCT HYPNOVEL. CONSEQUENTIALLY THE PIL AND LABEL HAVE BEEN UPDATED.
PL 10592/0162	BOOSTRIX SUSPENSION FOR INJECTION IN PFS	GRANTED	PL 10592/0162-0217	PL 10592/0162-0217	11/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SPC WITH DATA ON THE CO-ADMINISTRATION WITH UNADJUVANTED INACTIVATED SEASONAL INFLUENZA VACCINES AND NON-LIVE HERPES ZOSTER VACCINE SUPPORTED BY STUDY DTPA-0.3-008 FOR THE CO-ADMINISTRATION OF BOOSTRIX WITH UNADJUVANTED INACTIVATED SEASONAL INFLUENZA VACCINES AND STUDY ZOSTER-042 FOR THE

										CO-ADMINISTRATION OF BOOSTRIX WITH NON-LIVE HERPES ZOSTER VACCINE CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 10592/0162	DIPHTHERIA, TETANUS AND PERTUSSIS (ACELLULAR, COMPONENT) VACCINE	GRANTED	PL 10592/0162-0217	PL 10592/0162-0217	11/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS GROUPING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SPC WITH DATA ON THE CO-ADMINISTRATION WITH UNADJUVANTED INACTIVATED SEASONAL INFLUENZA VACCINES AND NON-LIVE HERPES ZOSTER VACCINE SUPPORTED BY STUDY DTPA-0.3-008 FOR THE CO-ADMINISTRATION OF BOOSTRIX WITH UNADJUVANTED INACTIVATED SEASONAL INFLUENZA VACCINES AND STUDY ZOSTER-042 FOR THE CO-ADMINISTRATION OF BOOSTRIX WITH NON-LIVE HERPES ZOSTER VACCINE CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 04854/0120	RIGEVIDON	GRANTED	PL 04854/0120-0022	PL 04854/0120-0022	11/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.2, 4.3, 4.4, 4.5, 4.8 AND 5.2 OF THE SMPC AND PIL IN LINE WITH THE REFERENCE PRODUCT MINIDRIL COATED TABLETS (PFIZER, 03.10.2019, AUTHORIZED VIA NATIONAL PROCEDURE IN FRANCE).
PL 04425/5900R	CLOMID 50MG TABLETS	GRANTED	PL 04425/5900R-0087	PL 04425/5900R-0087	11/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (COMPLEX) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC TO ACHIEVE AN HARMONIZED OUTCOME OF THE ASSESSMENT OF A VARIATION TO ADD THE INFORMATION REGARDING ANAPHYLAXIS, ANGIOEDEMA AND SEVERE CUTANEOUS ADVERSE REACTIONS (3 VARIATIONS) (ONLY ERYTHEMA MULTIFORME). MINOR CHANGES, AN ADMINISTRATIVE UPDATE AND A CORRECTION OF A TYPOGRAPHICAL ERROR, HAVE BEEN MADE TO SECTIONS 5.1 AND 9 OF THE SMPC. CONSEQUENTIALLY,

										THE PIL HAS BEEN UPDATED.
PL 04425/0214	FRISIUM TABLETS 10MG	GRANTED	PL 04425/0214-0078	PL 04425/0214-0078	16/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 AND 4.5 OF THE SPC IN LINE WITH CLINICAL DATA CONCERNING THE INFORMATION OF DRUG INTERACTION BETWEEN CLOBAZAM AND CANNABIDIOL-CONTAINING PRODUCTS. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET HAS ALSO BEEN UPDATED.
PL 00101/0212	OCTREOTIDE AMPOULES 50 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00101/0212-0134	PL 00101/0212-0134	18/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC, AND CONSEQUENTIALLY SECTION 2 OF THE PIL, CONCERNING INFORMATION ON CONCOMITANT TREATMENT WITH LUTATHERA (LUTETIUM (177 LU) OXODOTREOTIDE). SECTION 2 OF THE SMPC HAS ALSO BEEN REVISED TO REMOVE REFERENCE TO THE SODIUM CONTENT, AS IT DOES NOT MEET THE THRESHOLD FOR INCLUSION.

PL 00101/0212	SANDOSTATIN AMPOULES 50 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00101/0212-0134	PL 00101/0212-0134	18/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC, AND CONSEQUENTIALLY SECTION 2 OF THE PIL, CONCERNING INFORMATION ON CONCOMITANT TREATMENT WITH LUTATHERA (LUTETIUM (177 LU) OXODOTREOTIDE). SECTION 2 OF THE SMPC HAS ALSO BEEN REVISED TO REMOVE REFERENCE TO THE SODIUM CONTENT, AS IT DOES NOT MEET THE THRESHOLD FOR INCLUSION.
PL 00101/0213	OCTREOTIDE AMPOULES 100 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00101/0213-0132	PL 00101/0213-0132	18/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC, AND CONSEQUENTIALLY SECTION 2 OF THE PIL, CONCERNING INFORMATION ON CONCOMITANT TREATMENT WITH LUTATHERA (LUTETIUM (177 LU) OXODOTREOTIDE). SECTION 2 OF THE SMPC HAS ALSO BEEN REVISED TO REMOVE REFERENCE TO THE SODIUM CONTENT, AS IT DOES NOT MEET THE THRESHOLD FOR INCLUSION.

PL 00101/0213	SANDOSTATIN AMPOULES 100 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00101/0213-0132	PL 00101/0213-0132	18/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC, AND CONSEQUENTIALLY SECTION 2 OF THE PIL, CONCERNING INFORMATION ON CONCOMITANT TREATMENT WITH LUTATHERA (LUTETIUM (177 LU) OXODOTREOTIDE). SECTION 2 OF THE SMPC HAS ALSO BEEN REVISED TO REMOVE REFERENCE TO THE SODIUM CONTENT, AS IT DOES NOT MEET THE THRESHOLD FOR INCLUSION.
PL 00101/0214	OCTREOTIDE AMPOULES 500 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00101/0214-0130	PL 00101/0214-0130	18/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC, AND CONSEQUENTIALLY SECTION 2 OF THE PIL, CONCERNING INFORMATION ON CONCOMITANT TREATMENT WITH LUTATHERA (LUTETIUM (177 LU) OXODOTREOTIDE). SECTION 2 OF THE SMPC HAS ALSO BEEN REVISED TO REMOVE REFERENCE TO THE SODIUM CONTENT, AS IT DOES NOT MEET THE THRESHOLD FOR INCLUSION.

PL 00101/0214	SANDOSTATIN AMPOULES 500 MCG/ML SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00101/0214-0130	PL 00101/0214-0130	18/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC, AND CONSEQUENTIALLY SECTION 2 OF THE PIL, CONCERNING INFORMATION ON CONCOMITANT TREATMENT WITH LUTATHERA (LUTETIUM (177 LU) OXODOTREOTIDE). SECTION 2 OF THE SMPC HAS ALSO BEEN REVISED TO REMOVE REFERENCE TO THE SODIUM CONTENT, AS IT DOES NOT MEET THE THRESHOLD FOR INCLUSION.
PL 00101/0511	SANDOSTATIN LAR 10 MG POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 00101/0511-0121	PL 00101/0511-0121	18/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC, AND CONSEQUENTIALLY SECTION 2 OF THE PIL, CONCERNING INFORMATION ON CONCOMITANT TREATMENT WITH LUTATHERA (LUTETIUM (177 LU) OXODOTREOTIDE). SECTION 2 OF THE SMPC HAS ALSO BEEN REVISED TO REMOVE REFERENCE TO THE SODIUM CONTENT, AS IT DOES NOT MEET THE THRESHOLD FOR INCLUSION.

PL 00101/0512	SANDOSTATIN LAR 20 MG POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 00101/0512-0118	PL 00101/0512-0118	18/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC, AND CONSEQUENTIALLY SECTION 2 OF THE PIL, CONCERNING INFORMATION ON CONCOMITANT TREATMENT WITH LUTATHERA (LUTETIUM (177 LU) OXODOTREOTIDE). SECTION 2 OF THE SMPC HAS ALSO BEEN REVISED TO REMOVE REFERENCE TO THE SODIUM CONTENT, AS IT DOES NOT MEET THE THRESHOLD FOR INCLUSION.
PL 00101/0513	SANDOSTATIN LAR 30 MG POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	GRANTED	PL 00101/0513-0118	PL 00101/0513-0118	18/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.5 OF THE SMPC, AND CONSEQUENTIALLY SECTION 2 OF THE PIL, CONCERNING INFORMATION ON CONCOMITANT TREATMENT WITH LUTATHERA (LUTETIUM (177 LU) OXODOTREOTIDE). SECTION 2 OF THE SMPC HAS ALSO BEEN REVISED TO REMOVE REFERENCE TO THE SODIUM CONTENT, AS IT DOES NOT MEET THE THRESHOLD FOR INCLUSION.

PL 40861/0006	BINOSTO 70 MG EFFERVESCENT TABLETS	GRANTED	PL 40861/0006-0023	PL 40861/0006-0023	23/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 2, 4.4, 4.8 AND 5.1 OF THE SPC TO INTRODUCE THE INCIDENCE OF THE ADVERSE EVENTS REPORTED FROM THE STUDY ON GASTROINTESTINAL EVENTS AND MEDICATION ERRORS FOR STEOVESS /BINOSTO (UK/H/3515/001 - NEW DE/H/5609/001) AND TO CORRECT THE SODIUM CONTENT. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 08828/0144	FRESENIUS PROPOFOL 1%, EMULSION FOR INJECTION OR INFUSION	GRANTED	PL 08828/0144-0097	PL 08828/0144-0097	25/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 AND 5.3 OF THE SMPC AND PIL
PL 27925/0008	EASYHALER BUDESONIDE 100 MICROGRAMS PER ACTUATION INHALATION POWDER	GRANTED	PL 27925/0008-0061	PL 27925/0008-0061	25/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE THE RISK MANAGEMENT PLAN FOR THE FINISHED PRODUCT IN LINE WITH THE COMMITMENT AT THE END OF RUP PROCEDURE (DE/H/0402/H/001/E/003).
PL 27925/0009	EASYHALER BUDESONIDE 200 MICROGRAMS PER	GRANTED	PL 27925/0	PL 27925/0	25/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO INTRODUCE THE RISK MANAGEMENT PLAN FOR THE

	ACTUATION INHALATION POWDER		009-0060	009-0060				(STANDARD) - CMS		FINISHED PRODUCT IN LINE WITH THE COMMITMENT AT THE END OF RUP PROCEDURE (DE/H/0402/H/001/E/003).
PL 27925/0010	EASYHALER BUDESONIDE 400 MICROGRAMS PER ACTUATION INHALATION POWDER	GRANTED	PL 27925/0010-0059	PL 27925/0010-0059	25/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO INTRODUCE THE RISK MANAGEMENT PLAN FOR THE FINISHED PRODUCT IN LINE WITH THE COMMITMENT AT THE END OF RUP PROCEDURE (DE/H/0402/H/001/E/003).
PL 41549/0001	PRILIGY 30 MG FILM-COATED TABLETS	GRANTED	PL 41549/0001-0028	PL 41549/0001-0028	28/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	1. TO UPDATE THE RISK MANAGEMENT PLAN FROM VERSION 8.1 TO VERSION 9.0 2. CONSEQUENTIALLY, SECTION 6.5 OF THE SPC, THE PIL AND LABEL HAVE BEEN UPDATED.
PL 41549/0001	PRILIGY 30 MG FILM-COATED TABLETS	GRANTED	PL 41549/0001-0028	PL 41549/0001-0028	28/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	1. TO UPDATE THE RISK MANAGEMENT PLAN FROM VERSION 8.1 TO VERSION 9.0 2. CONSEQUENTIALLY, SECTION 6.5 OF THE SPC, THE PIL AND

										LABEL HAVE BEEN UPDATED.
PL 41549/0002	PRILIGY 60MG FILM-COATED TABLETS	GRANTED	PL 41549/0002-0028	PL 41549/0002-0028	28/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	1. TO UPDATE THE RISK MANAGEMENT PLAN FROM VERSION 8.1 TO VERSION 9.0 2. CONSEQUENTIALLY, SECTION 6.5 OF THE SPC, THE PIL AND LABEL HAVE BEEN UPDATED.
PL 41549/0002	PRILIGY 60MG FILM-COATED TABLETS	GRANTED	PL 41549/0002-0028	PL 41549/0002-0028	28/06/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	DECENTRALISED	1. TO UPDATE THE RISK MANAGEMENT PLAN FROM VERSION 8.1 TO VERSION 9.0 2. CONSEQUENTIALLY, SECTION 6.5 OF THE SPC, THE PIL AND LABEL HAVE BEEN UPDATED.
PL 34926/0016	IZINOVA CONCENTRATE FOR ORAL SOLUTION	GRANTED	PL 34926/0016-0048	PL 34926/0016-0048	01/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.4 OF THE SMPC AND PACKAGE LEAFLET IN ORDER TO INTEGRATE A NEW WARNING REGARDING THE RISK OF COLITIS ASSOCIATED WITH THE ADMINISTRATION OF COLONIC PREPARATIONS AND SECTION 02 OF THE

										SMPC IN LINE WITH QRD TEMPLATE.
PL 46654/0006	FULVESTRANT EVER PHARMA 250 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 46654/0006-0009	PL 46654/0006-0009	02/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	THIS CASE HAS BEEN REINSTATED AS PL 46654/0006 - 0008 WAS AUTO-INVALIDATED. THIS IS A CONTINUATION OF THE VCR FROM THE PREVIOUS PL SUBMISSION. TO UPDATE THE SMPC FRAGMENTS TO IMPLEMENT CHANGES TO THE PRODUCT INFORMATION RESULTING FROM COMMENTS OF THE NEW CMS AND FROM THE RMS'S ASSESSMENT DURING THE RUP.
PL 00003/0272	LAMICTAL TABLETS 25MG	GRANTED	PL 00003/0272-0148	PL 00003/0272-0148	05/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 5.2 AND 5.3 OF THE SMPC FRAGMENTS TO ADD A DRUG INTERACTION WITH PARACETAMOL, UPDATE EXISTING NON-CLINICAL INFORMATION, AND UPDATE MINOR EDITORIAL DETAILS.
PL 00003/0273	LAMICTAL TABLETS 50MG	GRANTED	PL 00003/0273-0145	PL 00003/0273-0145	05/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 5.2 AND 5.3 OF THE SMPC FRAGMENTS TO ADD A

								RD) - CMS WORKSHARING		DRUG INTERACTION WITH PARACETAMOL, UPDATE EXISTING NON-CLINICAL INFORMATION, AND UPDATE MINOR EDITORIAL DETAILS.
PL 00003/0274	LAMICTAL TABLETS 100MG	GRANTED	PL 00003/0274-0139	PL 00003/0274-0139	05/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 5.2 AND 5.3 OF THE SMPC FRAGMENTS TO ADD A DRUG INTERACTION WITH PARACETAMOL, UPDATE EXISTING NON-CLINICAL INFORMATION, AND UPDATE MINOR EDITORIAL DETAILS.
PL 00003/0297	LAMICTAL TABLETS 200MG	GRANTED	PL 00003/0297-0145	PL 00003/0297-0145	05/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 5.2 AND 5.3 OF THE SMPC FRAGMENTS TO ADD A DRUG INTERACTION WITH PARACETAMOL, UPDATE EXISTING NON-CLINICAL INFORMATION, AND UPDATE MINOR EDITORIAL DETAILS.
PL 00003/0347	LAMICTAL 25 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0347-0153	PL 00003/0347-0153	05/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 5.2 AND 5.3 OF THE SMPC FRAGMENTS TO ADD A DRUG INTERACTION WITH PARACETAMOL, UPDATE EXISTING NON-CLINICAL INFORMATION, AND

										UPDATE MINOR EDITORIAL DETAILS.
PL 00003/0348	LAMICTAL 100 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0348-0155	PL 00003/0348-0155	05/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 5.2 AND 5.3 OF THE SMPC FRAGMENTS TO ADD A DRUG INTERACTION WITH PARACETAMOL, UPDATE EXISTING NON-CLINICAL INFORMATION, AND UPDATE MINOR EDITORIAL DETAILS.
PL 00003/0368	LAMICTAL 50 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0368-0148	PL 00003/0368-0148	05/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 5.2 AND 5.3 OF THE SMPC FRAGMENTS TO ADD A DRUG INTERACTION WITH PARACETAMOL, UPDATE EXISTING NON-CLINICAL INFORMATION, AND UPDATE MINOR EDITORIAL DETAILS.
PL 00003/0369	LAMICTAL 200 MG CHEWABLE/DISPERSIBLE TABLETS	GRANTED	PL 00003/0369-0146	PL 00003/0369-0146	05/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 5.2 AND 5.3 OF THE SMPC FRAGMENTS TO ADD A DRUG INTERACTION WITH PARACETAMOL, UPDATE EXISTING NON-CLINICAL INFORMATION, AND UPDATE MINOR EDITORIAL DETAILS.
PL 00003/0375	LAMICTAL 2MG CHEWABLE/	GRANTED	PL 00003/0	PL 00003/0	05/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II	DECENTRALISED	TO UPDATE SECTIONS 4.2, 4.4, 4.5, 5.2 AND 5.3 OF THE SMPC

	DISPERSIBLE/ TABLETS		375-0125	375-0125				(STANDARD) - CMS WORKSHARING		FRAGMENTS TO ADD A DRUG INTERACTION WITH PARACETAMOL, UPDATE EXISTING NON-CLINICAL INFORMATION, AND UPDATE MINOR EDITORIAL DETAILS.
PL 04569/1754	NORTRIPTYLINE 10 MG FILM-COATED TABLETS	GRANTED	PL 04569/1754-0011	PL 04569/1754-0011	06/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.9 OF THE SMPC FRAGMENTS N LINE WITH THE REFERENCE MEDICINAL PRODUCT (NORTRILEN, LUNDBECK B.V.). CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04569/1755	NORTRIPTYLINE 25MG FILM-COATED TABLETS	GRANTED	PL 04569/1755-0010	PL 04569/1755-0010	06/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.9 OF THE SMPC FRAGMENTS N LINE WITH THE REFERENCE MEDICINAL PRODUCT (NORTRILEN, LUNDBECK B.V.). CONSEQUENTIALLY THE PIL HAS BEEN UPDATED.
PL 04569/1766	NORTRIPTYLINE 50 MG FILM-COATED TABLETS	GRANTED	PL 04569/1766-0005	PL 04569/1766-0005	06/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.9 OF THE SMPC IN LINE WITH THE REFERENCE MEDICINAL PRODUCT NORTRILEN 10 MG, 25 MG AND 50 MG FILM-COATED TABLETS (MAH: LUNDBECK B.V,

										AUTHORISED VIA NATIONAL PROCEDURE, MA NUMBERS: RVG 03285, RVG 03286, RVG 11407).
PL 10921/0023	COPAXONE 20MG/ML SOLUTION FOR INJECTION, PREFILLED SYRINGE	GRANTED	PL 10921/0023-0220	PL 10921/0023-0220	07/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FROM VERSION 4.2 TO VERSION 5. THE UPDATES ARE AS FOLLOW: - RE-CLASSIFICATION OF THE RISK OF ¿LIVER INJURY¿ FOLLOWING THE CONCLUSIONS FROM VARIATION PROCEDURE DE/H/5283/002,004/II/186. - ADDITION OF FEW MORE TRIGGER TERMS TO THE CURRENTLY APPROVED LIVER INJURY FOLLOW-UP QUESTIONNAIRE FOLLOWING THE ASSESSMENT ON DILI REPORT IN VARIATION PROCEDURE DE/H/5283/002,004/II/186. - UPDATE OF THE LIVER INJURY

										FOLLOW-UP QUESTIONNAIRE IN ORDER TO MAKE IT MORE COMPREHENSIVE IN PARTICULAR ON POSSIBLE LIVER INJURY CONTRIBUTING FACTORS.
PL 10921/0026	COPAXONE 40 MG/ML SOLUTION FOR INJECTION, PRE-FILLED SYRINGE	GRANTED	PL 10921/0026-0052	PL 10921/0026-0052	07/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO UPDATE THE RISK MANAGEMENT PLAN (RMP) FROM VERSION 4.2 TO VERSION 5. THE UPDATES ARE AS FOLLOW: - RE-CLASSIFICATION OF THE RISK OF ¿LIVER INJURY¿ FOLLOWING THE CONCLUSIONS FROM VARIATION PROCEDURE DE/H/5283/002,004/II/186. - ADDITION OF FEW MORE TRIGGER TERMS TO THE CURRENTLY APPROVED LIVER INJURY FOLLOW-UP QUESTIONNAIRE FOLLOWING THE ASSESSMENT ON DILI REPORT IN VARIATION PROCEDURE DE/H/5283/002,004/II/18

										6. - UPDATE OF THE LIVER INJURY FOLLOW-UP QUESTIONNAIRE IN ORDER TO MAKE IT MORE COMPREHENSIVE IN PARTICULAR ON POSSIBLE LIVER INJURY CONTRIBUTING FACTORS.
PL 04569/1500	PANTOPRAZOLE 20 MG GASTRO-RESISTANT TABLETS	GRANTED	PL 04569/1500-0051	PL 04569/1500-0051	12/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.3 OF THE SPC IN LINE WITH A RECENT UPDATE TO THE BRAND LEADER TEXT PROTIUM 20 MG GASTRO-RESISTANT TABLETS, MAH TAKEDA PRODUCTS IRELAND, PA 2229/010/001.
PL 04569/1501	PANTOPRAZOLE 40 MG GASTRO-RESISTANT TABLETS	GRANTED	PL 04569/1501-0053	PL 04569/1501-0053	12/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.3 OF THE SPC IN LINE WITH A RECENT UPDATE TO THE BRAND LEADER TEXT PROTIUM 20 MG GASTRO-RESISTANT TABLETS, MAH TAKEDA PRODUCTS IRELAND, PA 2229/010/001.
PL 17780/1007	SLOZEM 120MG CAPSULES	GRANTED	PL 17780/1	PL 17780/1	12/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC TO INCLUDE

			007-0007	007-0007				(STANDARD) - CMS WORKSHARING		INFORMATION CONCERNING THE TOPIC OF ACUTE RENAL FAILURE IN THE CONTEXT OF DILTIAZEM USE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 17780/1008	SLOZEM 180MG CAPSULES	GRANTED	PL 17780/1008-0007	PL 17780/1008-0007	12/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC TO INCLUDE INFORMATION CONCERNING THE TOPIC OF ACUTE RENAL FAILURE IN THE CONTEXT OF DILTIAZEM USE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 17780/1009	SLOZEM 240MG CAPSULES	GRANTED	PL 17780/1009-0007	PL 17780/1009-0007	12/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC TO INCLUDE INFORMATION CONCERNING THE TOPIC OF ACUTE RENAL FAILURE IN THE CONTEXT OF DILTIAZEM USE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 17780/1010	SLOZEM 300MG CAPSULES	GRANTED	PL 17780/1010-0007	PL 17780/1010-0007	12/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 4.4 OF THE SMPC TO INCLUDE INFORMATION CONCERNING THE TOPIC OF ACUTE

								WORKSHARING		RENAL FAILURE IN THE CONTEXT OF DILTIAZEM USE. CONSEQUENTLY, THE PIL HAS BEEN UPDATED.
PL 00603/0028	NAVELBINE 10MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 00603/0028-0103	PL 00603/0028-0103	14/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.4 AND 4.8 OF THE SMPC AND PIL WITH INFORMATION REGARDING ¿ACUTE RESPIRATORY DISTRESS SYNDROME¿.
PL 00057/0589	SAYANA 104 MG/0.65 ML SUSPENSION FOR INJECTION	GRANTED	PL 00057/0589-0092	PL 00057/0589-0092	19/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FOLLOWING THE ROUTINE ASSESSMENT OF FOLLOW UP ADDITIONAL PHARMACOVIGILANCE MEASURES (FUM) FOR DEPOT MEDROXYPROGESTERONE ACETATE SUBCUTANEOUS (DMPA-SC).
PL 00057/1093	SAYANA PRESS 104 MG/0.65 ML SUSPENSION FOR INJECTION	GRANTED	PL 00057/1093-0070	PL 00057/1093-0070	19/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FOLLOWING THE ROUTINE ASSESSMENT OF FOLLOW UP ADDITIONAL PHARMACOVIGILANCE MEASURES (FUM) FOR DEPOT MEDROXYPROGESTE

										RONE ACETATE SUBCUTANEOUS (DMPA-SC).
PL 00057/1498	SAYANAJECT 104 MG SUSPENSION FOR INJECTION	GRANTED	PL 00057/1498-0042	PL 00057/1498-0042	19/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FOLLOWING THE ROUTINE ASSESSMENT OF FOLLOW UP ADDITIONAL PHARMACOVIGILANCE MEASURES (FUM) FOR DEPOT MEDROXYPROGESTERONE ACETATE SUBCUTANEOUS (DMPA-SC).
PL 00057/1500	ELASHINE 104 MG SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 00057/1500-0044	PL 00057/1500-0044	19/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE THE RISK MANAGEMENT PLAN FOLLOWING THE ROUTINE ASSESSMENT OF FOLLOW UP ADDITIONAL PHARMACOVIGILANCE MEASURES (FUM) FOR DEPOT MEDROXYPROGESTERONE ACETATE SUBCUTANEOUS (DMPA-SC).
PL 04425/0041	RIFINAH 150/100MG TABLETS	GRANTED	PL 04425/0041-0108	PL 04425/0041-0108	20/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND PIL O ADD ¿PARADOXICAL DRUG REACTION¿ AS UNDESIRABLE EFFECTS FOR ALL ITS RIFAMPICIN,

										ETHAMBUTOL AND PYRAZINAMIDE CONTAINING PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/0042	RIFINAH 300/150MG COATED TABLETS	GRANTED	PL 04425/0042-0114	PL 04425/0042-0114	20/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND PIL O ADD ¿PARADOXICAL DRUG REACTION¿ AS UNDESIRABLE EFFECTS FOR ALL ITS RIFAMPICIN, ETHAMBUTOL AND PYRAZINAMIDE CONTAINING PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND

										INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/0051	RIFADIN FOR INFUSION 600MG	GRANTED	PL 04425/0051-0093	PL 04425/0051-0093	20/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND PIL O ADD ¿PARADOXICAL DRUG REACTION¿ AS UNDESIRABLE EFFECTS FOR ALL ITS RIFAMPICIN, ETHAMBUTOL AND PYRAZINAMIDE CONTAINING PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/0060	RIFATER TABLETS	GRANTED	PL 04425/0060-0110	PL 04425/0060-0110	20/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND PIL O ADD ¿PARADOXICAL DRUG REACTION¿ AS UNDESIRABLE EFFECTS FOR ALL ITS RIFAMPICIN,

										ETHAMBUTOL AND PYRAZINAMIDE CONTAINING PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/5915R	RIFADIN 150MG CAPSULES	GRANTED	PL 04425/5915R-0112	PL 04425/5915R-0112	20/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND PIL O ADD ¿PARADOXICAL DRUG REACTION¿ AS UNDESIRABLE EFFECTS FOR ALL ITS RIFAMPICIN, ETHAMBUTOL AND PYRAZINAMIDE CONTAINING PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND

										INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/5916R	RIFADIN 300MG CAPSULES	GRANTED	PL 04425/5916R-0112	PL 04425/5916R-0112	20/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND PIL O ADD ¿PARADOXICAL DRUG REACTION¿ AS UNDESIRABLE EFFECTS FOR ALL ITS RIFAMPICIN, ETHAMBUTOL AND PYRAZINAMIDE CONTAINING PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 04425/5917R	RIFADIN 100MG/5ML ORAL SUSPENSION	GRANTED	PL 04425/5917R-0093	PL 04425/5917R-0093	20/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTION 4.8 OF THE SMPC AND PIL O ADD ¿PARADOXICAL DRUG REACTION¿ AS UNDESIRABLE EFFECTS FOR ALL ITS RIFAMPICIN,

										ETHAMBUTOL AND PYRAZINAMIDE CONTAINING PRODUCTS (INCLUDING RIFAMPICIN IN COMBINATION WITH ISONIAZID AND PYRAZINAMIDE) TO ACHIEVE A HARMONIZED OUTCOME OF THE ASSESSMENT AND INFORMATION FOR THE PRODUCTS REGISTERED NATIONALLY IN EU COUNTRIES.
PL 46602/0005	DIPHTHERIA, TETANUS, PERTUSSIS AND POLIOMYELITIS (INACTIVATED) VACCINE	GRANTED	PL 46602/0005-0106	PL 46602/0005-0106	22/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER UPDATES TO THE PREGNANCY DATA IN THE PRODUCT INFORMATION AND TO FULFIL THE COMMITMENT POST-RUP IN PROCEDURE DE/H/0215/II/161/G, THE ACRONYMS IN THE PRODUCT INFORMATION HAVE BEEN HARMONISED. CONSEQUENTIALLY, SECTIONS 2, 4.1, 4.2, 4.3, 4.4, 4.6 AND 5.1 OF THE SPC, THE LABELS AND PILS HAVE BEEN UPDATED.

PL 46602/0005	REPEVAX, SUSPENSION FOR INJECTION IN A PRE-FILLED SYRINGE	GRANTED	PL 46602/0005-0106	PL 46602/0005-0106	22/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER UPDATES TO THE PREGNANCY DATA IN THE PRODUCT INFORMATION AND TO FULFIL THE COMMITMENT POST-RUP IN PROCEDURE DE/H/0215/II/161/G, THE ACRONYMS IN THE PRODUCT INFORMATION HAVE BEEN HARMONISED. CONSEQUENTIALLY, SECTIONS 2, 4.1, 4.2, 4.3, 4.4, 4.6 AND 5.1 OF THE SPC, THE LABELS AND PILS HAVE BEEN UPDATED.
PL 46602/0013	ADACEL, SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE, DIPHTHERIA, TETANUS, PERTUSSIS VACCINE	GRANTED	PL 46602/0013-0057	PL 46602/0013-0057	22/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO REGISTER UPDATES TO THE PREGNANCY DATA IN THE PRODUCT INFORMATION AND TO FULFIL THE COMMITMENT POST-RUP IN PROCEDURE DE/H/0215/II/161/G, THE ACRONYMS IN THE PRODUCT INFORMATION HAVE BEEN HARMONISED. CONSEQUENTIALLY, SECTIONS 2, 4.1, 4.2, 4.3, 4.4, 4.6 AND 5.1 OF THE SPC, THE LABELS AND PILS HAVE BEEN UPDATED.

PL 02855/0332	NIQUITIN MINT 2MG LOZENGES	GRANTED	PL 02855/0332-0006	PL 02855/0332-0006	23/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO REGISTER CHANGES TO FRAGMENT 4.3 OF THE SPC RELATING TO CONTRAINDICATIONS. 2. TO REGISTER CHANGES TO FRAGMENT 4.4 OF THE SPC TO UPDATE TEXT RELATING TO WARNINGS AND PRECAUTIONS FOLLOWING NEW PHARMACOVIGILANCE DATA. 3. TO REGISTER CHANGES TO 4,5 OF THE SPC TO UPDATE TEXT RELATING TO INTERACTION WITH OTHER MEDICINAL PRODUCTS FOLLOWING NEW PHARMACOVIGILANCE DATA. 4. TO REGISTER CHANGES TO FRAGMENT 4.6 OF THE SPC TO UPDATE TEXT RELATING TO

										PREGNANCY, FERTILITY AND LACTATION FOLLOWING NEW PHARMACOVIGILANCE DATA. 5. TO REGISTER CHANGES TO FRAGMENT 4.8 OF THE SPC TO UPDATE TEXT RELATING TO UNDESIRABLE EFFECTS FOLLOWING NEW PHARMACOVIGILANCE DATA. 6. TO REGISTER CHANGES TO FRAGMENT 4.9 OF THE SPC TO UPDATE TEXT RELATING OVERDOSE FOLLOWING NEW PHARMACOVIGILANCE DATA. 7. TO REGISTER CHANGES TO FRAGMENT 5.1 OF THE SPC TO UPDATE TEXT RELATING TO PHARMACOLOGICAL

										PROPERTIES FOLLOWING NEW PHARMACOVIGILANCE DATA. 8. TO REGISTER CHANGES TO FRAGMENT 5.3 OF THE SPC TO UPDATE TEXT RELATING TO PRECLINICAL SAFETY DATA FOLLOWING NEW PHARMACOVIGILANCE DATA. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 02855/0333	NIQUITIN MINT 4MG LOZENGES	GRANTED	PL 02855/0333-0006	PL 02855/0333-0006	23/07/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS GROUPING	MUTUAL RECOGNITION	1. TO REGISTER CHANGES TO FRAGMENT 4.3 OF THE SPC RELATING TO CONTRAINDICATIONS. 2. TO REGISTER CHANGES TO FRAGMENT 4.4 OF THE SPC TO UPDATE TEXT RELATING TO WARNINGS AND PRECAUTIONS FOLLOWING NEW

										PHARMACOVIGILANCE DATA. 3. TO REGISTER CHANGES TO 4,5 OF THE SPC TO UPDATE TEXT RELATING TO INTERACTION WITH OTHER MEDICINAL PRODUCTS FOLLOWING NEW PHARMACOVIGILANCE DATA. 4. TO REGISTER CHANGES TO FRAGMENT 4.6 OF THE SPC TO UPDATE TEXT RELATING TO PREGNANCY, FERTILITY AND LACTATION FOLLOWING NEW PHARMACOVIGILANCE DATA. 5. TO REGISTER CHANGES TO FRAGMENT 4.8 OF THE SPC TO UPDATE TEXT RELATING TO UNDESIRABLE EFFECTS FOLLOWING

										NEW PHARMACOVIGILANCE DATA. 6. TO REGISTER CHANGES TO FRAGMENT 4.9 OF THE SPC TO UPDATE TEXT RELATING OVERDOSE FOLLOWING NEW PHARMACOVIGILANCE DATA. 7. TO REGISTER CHANGES TO FRAGMENT 5.1 OF THE SPC TO UPDATE TEXT RELATING TO PHARMACOLOGICAL PROPERTIES FOLLOWING NEW PHARMACOVIGILANCE DATA. 8. TO REGISTER CHANGES TO FRAGMENT 5.3 OF THE SPC TO UPDATE TEXT RELATING TO PRECLINICAL SAFETY DATA FOLLOWING NEW PHARMACOVIGILANCE

										DATA. CONSEQUENTIALLY, THE LEAFLET HAS BEEN UPDATED.
PL 00025/0194	INNOVACE 5MG TABLETS	GRANTED	PL 00025/0194-0096	PL 00025/0194-0096	05/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4 AND 4.5 OF THE SMPC TO ALIGN THE EU PRODUCT INFORMATION OF RENITEC AND SYNERPRIL WITH A POST-HOC RECOMMENDATION MADE BY THE PRAC. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET IS UPDATED.
PL 00025/0195	INNOVACE 10MG TABLETS	GRANTED	PL 00025/0195-0085	PL 00025/0195-0085	05/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4 AND 4.5 OF THE SMPC TO ALIGN THE EU PRODUCT INFORMATION OF RENITEC AND SYNERPRIL WITH A POST-HOC RECOMMENDATION MADE BY THE PRAC. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET IS UPDATED.
PL 00025/0196	INNOVACE 20MG TABLETS	GRANTED	PL 00025/0196-0097	PL 00025/0196-0097	05/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDA	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4 AND 4.5 OF THE SMPC TO ALIGN THE EU PRODUCT

								RD) - CMS WORKSHARING		INFORMATION OF RENITEC AND SYNERPRIL WITH A POST-HOC RECOMMENDATION MADE BY THE PRAC. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET IS UPDATED.
PL 00025/0220	INNOVACE 2.5MG TABLETS	GRANTED	PL 00025/0220-0097	PL 00025/0220-0097	05/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.3, 4.4 AND 4.5 OF THE SMPC TO ALIGN THE EU PRODUCT INFORMATION OF RENITEC AND SYNERPRIL WITH A POST-HOC RECOMMENDATION MADE BY THE PRAC. CONSEQUENTLY, THE PATIENT INFORMATION LEAFLET IS UPDATED.
PL 12288/0002	TECHNESCAN MIBI 1MG KIT FOR RADIOPHARMACEUTICAL PREPARATION	GRANTED	PL 12288/0002-0023	PL 12288/0002-0023	05/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTION 4.5 OF THE SPC IN LINE WITH PRAC RECOMMENDATIONS TO ADD A SPECIAL WARNING BASED ON THE ASSOCIATION BETWEEN PROTON PUMP INHIBITORS (PPIS) AND INCREASED STOMACH WALL UPTAKE, LEADING TO CONSEQUENTLY POORER SCAN

										QUALITY (PSUSA/00002868/201706). CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 10592/0209	DIPHTHERIA, TETANUS, PERTUSSIS AND POLIOMYELITIS (INACTIVATED) VACCINE	GRANTED	PL 10592/0209-0215	PL 10592/0209-0215	10/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE IB - CMS RMP	MUTUAL RECOGNITION	TO REGISTER THE INTRODUCTION OF A RISK MANAGEMENT PLAN, VERSION 1 FOR INFANRIX TETRA (DTPA-IPV) VACCINE, REQUESTED AS PART OF THE DAY 0 REPEAT USE PROCEDURE (FR/H/0251/002/E/001).
PL 10592/0209	INFANRIX-IPV, SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED	PL 10592/0209-0215	PL 10592/0209-0215	10/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE IB - CMS RMP	MUTUAL RECOGNITION	TO REGISTER THE INTRODUCTION OF A RISK MANAGEMENT PLAN, VERSION 1 FOR INFANRIX TETRA (DTPA-IPV) VACCINE, REQUESTED AS PART OF THE DAY 0 REPEAT USE PROCEDURE (FR/H/0251/002/E/001).
PLNI 15413/0136	ROCURONIUM BROMIDE 10 MG/ML SOLUTION FOR INJECTION/INFUSION	GRANTED	PLNI 15413/0136-0002	PLNI 15413/0136-0002	10/08/2021	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 ACCORDING TO THE COMMITMENT MADE DURING REPEAT USE PROCEDURE.
PL 08828/0155	PROPOFOL 2% FRESENIUS, EMULSION FOR INJECTION OR INFUSION	GRANTED	PL 08828/0155-0074	PL 08828/0155-0074	17/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.8 AND 5.3 OF THE SMPC AND PIL

PL 27925/0068	BUSPIRONE 5 MG TABLETS	GRANTED	PL 27925/0068-0038	PL 27925/0068-0038	17/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO REGISTER THE INTRODUCTION OF A RISK MANAGEMENT PLAN, VERSION 1 DUE TO UPCOMING REPEAT USE PROCEDURE.
PL 27925/0069	BUSPIRONE 10 MG TABLETS	GRANTED	PL 27925/0069-0036	PL 27925/0069-0036	17/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO REGISTER THE INTRODUCTION OF A RISK MANAGEMENT PLAN, VERSION 1 DUE TO UPCOMING REPEAT USE PROCEDURE.
PL 04425/0883	IBUPROFEN AND CAFFEINE SANOFI 400 MG/100 MG FILM-COATED TABLETS	GRANTED	PL 04425/0883-0010	PL 04425/0883-0010	20/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.3 OF THE SMPC TO DELETE THE ACTIVE SUBSTANCE IBUPROFEN MAY SHOW AND ENVIRONMENTAL RISK FOR THE AQUATIC ENVIRONMENT, ESPECIALLY FOR FISH (SEE SECTION 6.6).¿) AND SECTIONS 6.6 TO DELETE ¿THIS MEDICINAL PRODUCT MAY POSE A RISK TO THE ENVIRONMENT (SEE SECTION 5.3).¿).
PL 53886/0034	IBUPROFEN AND CAFFEINE SANOFI 400 MG/100 MG FILM-COATED TABLETS	GRANTED	PL 53886/0034-0005	PL 53886/0034-0005	20/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTION 5.3 OF THE SMPC TO DELETE THE ACTIVE SUBSTANCE IBUPROFEN MAY SHOW AND ENVIRONMENTAL RISK FOR THE AQUATIC

										ENVIRONMENT, ESPECIALLY FOR FISH (SEE SECTION 6.6).¿) AND SECTIONS 6.6 TO DELETE ¿THIS MEDICINAL PRODUCT MAY POSE A RISK TO THE ENVIRONMENT (SEE SECTION 5.3).¿).
PL 14894/0565	MONTELUKAST RANBAXY 4 MG CHEWABLE TABLETS	GRANTED	PL 14894/0565-0033	PL 14894/0565-0033	25/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.4 AND 4.6 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT, SINGULAIR 4 MG AND SINGULAIR 5 MG CHEWABLE TABLETS, AND THE EXCIPIENT GUIDELINE FOR THE EXCIPIENTS SODIUM AND MANNITOL. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 14894/0566	MONTELUKAST RANBAXY 5 MG CHEWABLE TABLETS	GRANTED	PL 14894/0566-0039	PL 14894/0566-0039	25/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	DECENTRALISED	TO UPDATE SECTIONS 4.4 AND 4.6 OF THE SPC IN LINE WITH THE REFERENCE PRODUCT, SINGULAIR 4 MG AND SINGULAIR 5 MG CHEWABLE TABLETS, AND THE EXCIPIENT GUIDELINE FOR THE EXCIPIENTS SODIUM AND MANNITOL. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.

PL 42956/0001	UVADEX 20 MICROGRAMS/ML SOLUTION FOR BLOOD FRACTION MODIFICATION	GRANTED	PL 42956/0001-0028	PL 42956/0001-0028	25/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 1, 4.1, 4.2, 4.4, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 6.2 AND 6.6 OF THE SPC WITH POST MARKETING ADRS FOLLOWING ANNUAL CCDS REVIEW AND IN LINE WITH THE EXCIPIENT GUIDELINE AND QRD TEMPLATE. CONSEQUENTIALLY, THE PIL HAS BEEN UPDATED.
PL 20117/0209	BUPRENORPHINE 0.4MG SUBLINGUAL TABLETS	GRANTED	PL 20117/0209-0037	PL 20117/0209-0037	25/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO INTRODUCE RISK MANAGEMENT PLAN: VERSION 1.0
PL 20117/0209	NATZON 0.4MG SUBLINGUAL TABLET	GRANTED	PL 20117/0209-0037	PL 20117/0209-0037	25/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS RMP	MUTUAL RECOGNITION	TO INTRODUCE RISK MANAGEMENT PLAN: VERSION 1.0
PL 00426/0074	BOTOX 100 ALLERGAN UNITS - POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 00426/0074-0208	PL 00426/0074-0208	25/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO REGISTER AN UPDATE TO FRAGMENTS 4.4 AND 4.8 TO UPDATE WITH REGARDS TO `WORSENING OF MIGRAINE' UNDER SECTION 4.8 AND BY REFERRING TO THE SODIUM EXCIPIENT CONTENT IN ORDER

										TO REFLECT THE LATEST EXCIPIENT EUROPEAN GUIDANCE (EMA/CHMP/302620/2017). ADDITIONALLY THE SPC HAS BEEN UPDATED TO REFLECT THE LATEST QRD TEMPLATE (V10.1) BY THE ADDITION OF THE TRACEABILITY STATEMENT. CONSEQUENTIAL CHANGES HAVE BEEN MADE TO THE PIL.
PL 00426/0118	BOTOX 50 ALLERGAN UNITS, POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 00426/0118-0129	PL 00426/0118-0129	25/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO REGISTER AN UPDATE TO FRAGMENTS 4.4 AND 4.8 TO UPDATE WITH REGARDS TO `WORSENING OF MIGRAINE' UNDER SECTION 4.8 AND BY REFERRING TO THE SODIUM EXCIPIENT CONTENT IN ORDER TO REFLECT THE LATEST EXCIPIENT EUROPEAN GUIDANCE (EMA/CHMP/302620/2017). ADDITIONALLY THE SPC HAS BEEN UPDATED TO REFLECT THE LATEST QRD TEMPLATE (V10.1) BY THE ADDITION OF THE TRACEABILITY STATEMENT. CONSEQUENTIAL

										CHANGES HAVE BEEN MADE TO THE PIL.
PL 00426/0119	BOTOX 200 ALLERGAN UNITS, POWDER FOR SOLUTION FOR INJECTION	GRANTED	PL 00426/0119-0117	PL 00426/0119-0117	25/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS WORKSHARING	DECENTRALISED	TO REGISTER AN UPDATE TO FRAGMENTS 4.4 AND 4.8 TO UPDATE WITH REGARDS TO `WORSENING OF MIGRAINE' UNDER SECTION 4.8 AND BY REFERRING TO THE SODIUM EXCIPIENT CONTENT IN ORDER TO REFLECT THE LATEST EXCIPIENT EUROPEAN GUIDANCE (EMA/CHMP/302620/2017). ADDITIONALLY THE SPC HAS BEEN UPDATED TO REFLECT THE LATEST QRD TEMPLATE (V10.1) BY THE ADDITION OF THE TRACEABILITY STATEMENT. CONSEQUENTIAL CHANGES HAVE BEEN MADE TO THE PIL.
PL 04515/0098	ACICLOVIR 25 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GRANTED	PL 04515/0098-0105	PL 04515/0098-0105	31/08/2021	VARIATION	TYPE II	VARV MEDICAL TYPE II (STANDARD) - CMS	MUTUAL RECOGNITION	TO UPDATE SECTIONS 4.1-4.9, 5.1-5.3, 6.5 AND 6.6 OF THE SMPC AND PIL IN LINE WITH THE NEW REFERENCE PRODUCT ZOVIRAZ IV IE.
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