



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 July 2026
EMA/PRAC/141965/2026
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 06-09 July 2026

Chair: Ulla Wändel Liminga – Vice-Chair: Liana Martirosyan

06 July 2026, 13:00 – 19:30, room 1C

07 July 2026, 08:30 – 19:30, room 1C

08 July 2026, 08:30 – 19:30, room 1C

09 July 2026, 08:30 – 16:00, room 1C

Organisational, regulatory and methodological matters (ORGAM)

23 July 2026, via teleconference

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also change during the course of the review. Additional details on some of these procedures will be published in the PRAC meeting highlights once the procedures are finalised.

Of note, this agenda is a working document primarily designed for PRAC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents ([EMA/127362/2006 Rev.1](#)).



Table of contents

1.	Introduction	11
1.1.	Welcome and declarations of interest of members, alternates and experts.....	11
1.2.	Agenda of the meeting on 06-09 July 2026	11
1.3.	Minutes of the previous meeting on 08-11 June 2026	11
2.	EU referral procedures for safety reasons: urgent EU procedures	11
2.1.	Newly triggered procedures	11
2.2.	Ongoing procedures	11
2.3.	Procedures for finalisation.....	11
3.	EU referral procedures for safety reasons: other EU referral procedures	11
3.1.	Newly triggered procedure	11
3.2.	Ongoing procedures	11
3.3.	Procedures for finalisation.....	12
3.4.	Re-examination procedures.....	12
3.5.	Others	12
4.	Signals assessment and prioritisation	12
4.1.	New signals detected from EU spontaneous reporting systems and/or other sources	12
4.1.1.	Atogepant - AQUIPTA (CAP).....	12
4.1.2.	Atogepant - AQUIPTA (CAP); Erenumab – AIMOVIG (CAP); eptinezumab - VYEPTI (CAP); fremanezumab – AJOVY (CAP); galcanezumab – EMGALITY (CAP); rimegepant - VYDURA (CAP)	12
4.1.3.	Oseltamivir – TAMIFLU (CAP); zanamivir – DECTOVA (CAP).....	13
4.1.4.	Sacituzumab govitecan - TRODELVY (CAP)	13
4.1.5.	Selpercatinib – RETSEVMO (CAP).....	13
4.1.6.	Sevoflurane (NAP)	13
4.2.	Signals follow-up and prioritisation	14
4.2.1.	Desogestrel (NAP), etonogestrel (NAP).....	14
4.2.2.	Levonorgestrel intrauterine device 13.5 mg (Jaydess/Flere) (NAP)	14
4.2.3.	Venlafaxine (NAP).....	14
4.3.	Variation procedure(s) resulting from signal evaluation	14
5.	Risk management plans (RMPs)	14
5.1.	Medicines in the pre-authorisation phase	14
5.1.1.	Denecimig - (CAP MAA) - EMEA/H/C/006344.....	14
5.1.2.	Gefurulumab - (CAP MAA) - EMEA/H/C/006558	15
5.1.3.	Navepegritide - (CAP MAA) - EMEA/H/C/006627, Orphan.....	15

5.1.4.	Pegfilgrastim - (CAP MAA) - EMEA/H/C/006937	15
5.1.5.	Pertuzumab - (CAP MAA) - EMEA/H/C/006844.....	15
5.1.6.	Povorcitinib - (CAP MAA) - EMEA/H/C/006727	15
5.1.7.	Relacorilant - (CAP MAA) - EMEA/H/C/006731, Orphan.....	15
5.1.8.	Riociguat - (CAP MAA) - EMEA/H/C/006838	15
5.1.9.	Ruxolitinib - (CAP MAA) - EMEA/H/C/006791.....	15
5.1.10.	Tofacitinib - (CAP MAA) - EMEA/H/C/006698.....	16
5.1.11.	Zamtocabtagene autoleucel - (CAP MAA) - EMEA/H/C/005495, PRIME, Orphan	16
5.2.	Medicines in the post-authorisation phase – PRAC-led procedures.....	16
5.2.1.	Adalimumab – HUMIRA (CAP) – EMA/VR/0000342430.....	16
5.2.2.	Cabozantinib – CABOMETYX (CAP); COMETRIQ (CAP) – EMA/VR/0000338165.....	16
5.2.3.	Siponimod – MAYZENT (CAP) – EMA/VR/0000317924	16
5.3.	Medicines in the post-authorisation phase – CHMP-led procedures	17
5.3.1.	Alpelisib – PIQRAY (CAP) – EMA/VR/0000317159	17
5.3.2.	Angiotensin II – GIAPREZA (CAP) – EMA/VR/0000343583	17
5.3.3.	Asciminib – SCEMBLIX (CAP) – EMA/VR/0000342126.....	17
5.3.4.	Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence – STRIMVELIS (CAP) – EMA/VR/0000347859	18
5.3.5.	Bictegravir / Emtricitabine / Tenofovir alafenamide – BIKTARVY (CAP) – EMA/VR/0000339784	18
5.3.6.	Cabotegravir – VOCABRIA (CAP) – EMA/VR/0000332087.....	18
5.3.7.	Cabotegravir – APRETUDE (CAP) – EMA/VR/0000331993.....	18
5.3.8.	Cemiplimab – LIBTAYO (CAP) – EMA/VR/0000347296	19
5.3.9.	Dimethyl fumarate – TECFIDERA (CAP) – EMA/VR/0000320745	19
5.3.10.	Dolutegravir / Lamivudine – DOVATO (CAP) – EMA/X/0000335457.....	19
5.3.11.	Eravacycline – XERAVA (CAP) – EMA/VR/0000343900.....	20
5.3.12.	Etranacogene dezaparovec – HEMGENIX (CAP) – EMA/VR/0000347644	20
5.3.13.	Evolocumab – REPATHA (CAP) – EMA/VR/0000322435.....	20
5.3.14.	Faricimab – VABYSMO (CAP) – EMA/VR/0000308736	21
5.3.15.	Fedratinib – INREBIC (CAP) – EMA/VR/0000324950.....	21
5.3.16.	Glycopyrronium – SIALANAR (CAP) – EMA/X/0000287532	22
5.3.17.	Insulin icodec / Semaglutide – KYINSU (CAP) – EMA/VR/0000322527	22
5.3.18.	Lacosamide – LACOSAMIDE UCB (CAP); VIMPAT (CAP) – EMA/VR/0000321459.....	22
5.3.19.	Mavacamten – CAMZYOS (CAP) – EMA/VR/0000343906	22
5.3.20.	Nusinersen – SPINRAZA (CAP) – EMA/VR/0000343403	23
5.3.21.	Osimertinib – TAGRISSO (CAP) – EMA/VR/0000340013.....	23
5.3.22.	Pandemic influenza vaccine (H5N1) (live attenuated, nasal) – PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) – EMA/VR/0000321324.....	23
5.3.23.	Pembrolizumab – KEYTRUDA (CAP) – EMA/VR/0000340550	24

5.3.24.	Pemigatinib – PEMAZYRE (CAP) – EMA/VR/0000343983	24
5.3.25.	Respiratory syncytial virus vaccine (bivalent, recombinant) – ABRYSCO (CAP) – EMA/VR/0000343072	24
5.3.26.	Sacituzumab govitecan – TRODELVY (CAP) – EMA/VR/0000320818	25
5.3.27.	Secukinumab – COSENTYX (CAP) – EMA/VR/0000340032	25
5.3.28.	Semaglutide – WEGOVY (CAP) – EMA/VR/0000327359.....	25
5.3.29.	Tafasitamab – MINJUVI (CAP) – EMA/VR/0000339938	26
5.3.30.	Talquetamab – TALVEY (CAP) – EMA/VR/0000339914	26
5.3.31.	Tucatinib – TUKYSA (CAP) – EMA/VR/0000341660.....	26
5.3.32.	Upadacitinib – RINVOQ (CAP) – EMA/X/0000304823.....	27
5.3.33.	Vamorolone – AGAMREE (CAP) – EMA/VR/0000343140	27
5.3.34.	Vedolizumab – ENTYVIO (CAP) – EMA/VR/0000340504	27
5.3.35.	Vosoritide – VOXZOGO (CAP) – EMA/VR/0000343152	28

6. Periodic safety update reports (PSURs) 28

6.1.	PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) only	28
6.1.1.	Acidinium / Formoterol fumarate dihydrate – BRIMICA GENUAIR (CAP); DUAKLIR GENUAIR (CAP) – EMA/PSUR/0000336119	28
6.1.2.	Adagrasib – KRAZATI (CAP) – EMA/PSUR/0000336084	28
6.1.3.	Aflibercept – AFIVEG (CAP); AFQLIR (CAP); AHZANTIVE (CAP); BAIAMA (CAP); EIYZEY (CAP); EYDENZELT (CAP); EYLEA (CAP); EYLUXVI (CAP); MYNZEPLI (CAP); OPUVIZ (CAP); PAVBLU (CAP); VGENFLI (CAP); YESAFILI (CAP) – EMA/PSUR/0000336116.....	28
6.1.4.	Arpraziquantel – ARPRAZIQUNTEL (Art 58) – EMA/PSUR/0000333585.....	29
6.1.5.	Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence – STRIMVELIS (CAP) – EMA/PSUR/0000336165	29
6.1.6.	Benralizumab – FASENRA (CAP) – EMA/PSUR/0000336112.....	29
6.1.7.	Blinatumomab – BLINCYTO (CAP) – EMA/PSUR/0000336108	29
6.1.8.	Budesonide – KINPEYGO (CAP) – EMA/PSUR/0000336136.....	29
6.1.9.	Concentrate of proteolytic enzymes enriched in bromelain – NEXOBRID (CAP) – EMA/PSUR/0000336099	30
6.1.10.	COVID-19 vaccine (recombinant, adjuvanted) – NUVAXOVID (CAP) – EMA/PSUR/0000336124	30
6.1.11.	Datopotamab deruxtecan – DATROWAY (CAP) – EMA/PSUR/0000336154	30
6.1.12.	Deutivacaftor / Tezacaftor / Vanzacaftor – ALYFTREK (CAP) – EMA/PSUR/0000336139	30
6.1.13.	Efgartigimod alfa – VYVGART (CAP) – EMA/PSUR/0000336133.....	30
6.1.14.	Elacestrant – ORSERDU (CAP) – EMA/PSUR/0000336096	31
6.1.15.	Elafibranor – IQIRVO (CAP) – EMA/PSUR/0000336148	31
6.1.16.	Enfortumab vedotin – PADCEV (CAP) – EMA/PSUR/0000336134.....	31
6.1.17.	Entrectinib – ROZLYTREK (CAP) – EMA/PSUR/0000336153	31
6.1.18.	Eplontersen – WAINZUA (CAP) – EMA/PSUR/0000336131.....	31

6.1.19.	Ferric citrate coordination complex – XOANACYL (CAP) – EMA/PSUR/0000336132	31
6.1.20.	Flortaucipir (18F) – TAUVID (CAP) – EMA/PSUR/0000336149.....	32
6.1.21.	Givinostat – DUVYZAT (CAP) – EMA/PSUR/0000336164	32
6.1.22.	Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) – CERVARIX (CAP) – EMA/PSUR/0000336113	32
6.1.23.	Hydroxocobalamin – CYANOKIT (CAP) – EMA/PSUR/0000336100	32
6.1.24.	Ibrutinib – IMBRUVICA (CAP) – EMA/PSUR/0000336107.....	32
6.1.25.	Imetelstat – RYTELO (CAP) – EMA/PSUR/0000336130.....	33
6.1.26.	Inclisiran – LEQVIO (CAP) – EMA/PSUR/0000336155	33
6.1.27.	Inotuzumab ozogamicin – BESPONSA (CAP) – EMA/PSUR/0000336115	33
6.1.28.	Iptacopan – FABHALTA (CAP) – EMA/PSUR/0000336141	33
6.1.29.	Ixazomib – NINLARO (CAP) – EMA/PSUR/0000336109	33
6.1.30.	Levodopa – INBRIJA (CAP) – EMA/PSUR/0000336140	33
6.1.31.	Mosunetuzumab – LUNSUMIO (CAP) – EMA/PSUR/0000336142.....	34
6.1.32.	Nirmatrelvir / Ritonavir – PAXLOVID (CAP) – EMA/PSUR/0000336147	34
6.1.33.	Octreotide – OCZYESA (CAP) – EMA/PSUR/0000336143	34
6.1.34.	Olezarsen – TRYNGOLZA (CAP) – EMA/PSUR/0000336151.....	34
6.1.35.	Padeliporfin – TOOKAD (CAP) – EMA/PSUR/0000336122	34
6.1.36.	Pegvisomant – SOMAVERT (CAP) – EMA/PSUR/0000336093	35
6.1.37.	Pegzilarginase – LOARGYS (CAP) – EMA/PSUR/0000336083.....	35
6.1.38.	Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) – PREVENAR 20 (CAP) – EMA/PSUR/0000336138	35
6.1.39.	Pneumococcal polysaccharide conjugate vaccine (21-valent) – CAPVAXIVE (CAP) – EMA/PSUR/0000336152	35
6.1.40.	Prasterone – INTRAROSA (CAP) – EMA/PSUR/0000336121	35
6.1.41.	Respiratory syncytial virus mRNA vaccine (nucleoside modified) – MRESVIA (CAP) – EMA/PSUR/0000336146	35
6.1.42.	Ritlecitinib – LITFULO (CAP) – EMA/PSUR/0000336091	36
6.1.43.	Roxadustat – EVRENZO (CAP) – EMA/PSUR/0000336126.....	36
6.1.44.	Sepiapterin – SEPHIENCE (CAP) – EMA/PSUR/0000336127.....	36
6.1.45.	Sipavibart – KAVIGALE (CAP) – EMA/PSUR/0000336123	36
6.1.46.	Sugemalimab – CEJEMLY (CAP) – EMA/PSUR/0000336144	36
6.1.47.	Susoctocog alfa – OBIZUR (CAP) – EMA/PSUR/0000336105.....	37
6.1.48.	Tabelecleucel – EBVALLO (CAP) – EMA/PSUR/0000336145	37
6.1.49.	Tezepelumab – TEZSPIRE (CAP) – EMA/PSUR/0000336135	37
6.1.50.	Tirbanibulin – KLISYRI (CAP) – EMA/PSUR/0000336129	37
6.1.51.	Tislelizumab – TEVIMBRA (CAP) – EMA/PSUR/0000336087.....	37
6.1.52.	Toripalimab – LOQTORZI (CAP) – EMA/PSUR/0000336150.....	37
6.1.53.	Tralokinumab – ADTRALZA (CAP) – EMA/PSUR/0000336125.....	38
6.1.54.	Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/PSUR/0000336128.....	38

6.1.55.	Ublituximab – BRIUMVI (CAP) – EMA/PSUR/0000336163.....	38
6.1.56.	Vadadustat – VAFSEO (CAP) – EMA/PSUR/0000336137.....	38
6.2.	PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) and nationally authorised products (NAPs)	38
6.2.1.	Clopidogrel – CLOPIDOGREL ZENTIVA (CAP); ISCOVER (CAP); PLAVIX (CAP); Clopidogrel / Acetylsalicylic acid – DUOPLAVIN (CAP); NAP – EMA/PSUR/0000336095	38
6.2.2.	Edotreotide – SOMAKIT TOC (CAP); NAP – EMA/PSUR/0000336114.....	39
6.3.	PSUR single assessment (PSUSA) procedures including nationally authorised products (NAPs) only	39
6.3.1.	Apomorphine – EMA/PSUR/0000336097	39
6.3.2.	Ascorbic acid / rutoside, ascorbic acid / rutoside / alfatocopherol – EMA/PSUR/000033610439	
6.3.3.	Benazepril – EMA/PSUR/0000336080	39
6.3.4.	Benzalkonium / benzocaine / tyrothricin – EMA/PSUR/0000336111.....	39
6.3.5.	Benzalkonium chloride / isopropyl myristate / paraffin liquid, benzalkonium chloride / chlorhexidine / isopropyl myristate / paraffin liquid – EMA/PSUR/0000336117	40
6.3.6.	Biclotymol / enoxolone / muramidase hydrochloride – EMA/PSUR/0000336089	40
6.3.7.	Brotizolam – EMA/PSUR/0000336092.....	40
6.3.8.	Caffeine / dimenhydrinate, dimenhydrinate – EMA/PSUR/0000336086	40
6.3.9.	Caffeine / ergotamine – EMA/PSUR/0000336078	40
6.3.10.	Caffeine / paracetamol / propyphenazone, paracetamol / propyphenazone – EMA/PSUR/0000336094	41
6.3.11.	Carbaethopendecinium bromide / trimecaine hydrochloride – EMA/PSUR/0000336106	41
6.3.12.	Chlorhexidine gluconate / isopropyl alcohol (covers other synonymous terms such as 2-propanol) – EMA/PSUR/0000336079	41
6.3.13.	Choline salicylate – EMA/PSUR/0000336077	41
6.3.14.	Clomifene – EMA/PSUR/0000336082.....	41
6.3.15.	Dienogest – EMA/PSUR/0000336102.....	41
6.3.16.	Idarubicin – EMA/PSUR/0000336098.....	42
6.3.17.	Indapamide – EMA/PSUR/0000336085	42
6.3.18.	Naltrexone – EMA/PSUR/0000336088	42
6.3.19.	Pancuronium – EMA/PSUR/0000336090	42
6.3.20.	Phenylephrine / tropicamide – EMA/PSUR/0000336103	42
6.3.21.	Sultamicillin – EMA/PSUR/0000336101.....	43
6.3.22.	Vecuronium bromide – EMA/PSUR/0000336110	43
6.3.23.	Yellow fever vaccine (live) – EMA/PSUR/0000337795	43
6.4.	Follow-up to PSUR/PSUSA procedures	43
6.4.1.	Rotavirus vaccine, live – ROTARIX (CAP) – EMA/PAM/0000343686	43
6.5.	Variation procedure(s) resulting from PSUSA evaluation	43
6.5.1.	Zilucoplan – ZILBRYSQ (CAP) – EMA/VR/0000343399	43
6.6.	Expedited summary safety reviews	44

7.	Post-authorisation safety studies (PASS)	44
7.1.	Protocols of PASS imposed in the marketing authorisation(s)	44
7.1.1.	Beremagene geperpavec – VYJUVEK (CAP) – EMA/PASS/0000287685	44
7.2.	Protocols of PASS non-imposed in the marketing authorisation(s)	44
7.2.1.	Cabotegravir – APRETUDE (CAP) – EMA/PAM/0000343607.....	44
7.2.2.	Chikungunya vaccine (live) – IXCHIQ (CAP) – EMA/PAM/0000341603	45
7.2.3.	Cladribine – MAVENCLAD (CAP) – EMA/PAM/0000319565	45
7.2.4.	Inebilizumab – UPLIZNA (CAP) – EMA/PAM/0000325493	45
7.2.5.	Levacetylleucine – AQNEURSA (CAP) – EMA/PAM/0000340768.....	45
7.2.6.	Maribavir – LIVTENCITY (CAP) – EMA/PAM/0000343616.....	45
7.2.7.	Rimegepant – VYDURA (CAP) – EMA/PAM/0000343596	46
7.3.	Results of PASS imposed in the marketing authorisation(s)	46
7.3.1.	Blinatumomab – BLINCYTO (CAP) – EMA/PASS/0000262863	46
7.3.2.	Sodium valproate (NAP) – EMA/PASS/0000287665	46
7.4.	Results of PASS imposed and non-imposed in the marketing authorisation(s)	47
7.4.1.	Brexpiprazole – RXULTI (CAP) – EMA/VR/0000340645	47
7.4.2.	Eslicarbazepine acetate – ZEBINIX (CAP) – EMA/VR/0000332409	47
7.4.3.	Nirmatrelvir / Ritonavir – PAXLOVID (CAP) – EMA/VR/0000339731.....	47
7.4.4.	Ofatumumab – KESIMPTA (CAP) – EMA/VR/0000315689.....	47
7.4.5.	Radium-223 – XOFIGO (CAP) – EMA/VR/0000333243	48
7.5.	Interim results and other post-authorisation measures for imposed and non-imposed studies	48
7.5.1.	Diroximel fumarate – VUMERITY (CAP) – EMA/PAM/0000343706.....	48
7.5.2.	Pegvaliase – PALYNZIQ (CAP) – EMA/PAM/0000319171.....	48
7.5.3.	Pegvaliase – PALYNZIQ (CAP) – EMA/PAM/0000317250.....	48
7.5.4.	Respiratory syncytial virus mRNA vaccine (nucleoside modified) – MRESVIA (CAP) – EMA/PAM/0000316615.....	49
7.5.5.	Selexipag – UPTRAVI (CAP) – EMA/PAM/0000309454.....	49
7.5.6.	Tezepelumab – TEZSPIRE (CAP) – EMA/PAM/0000343681	49
8.	Renewals of the marketing authorisation, conditional renewal and annual reassessments	49
8.1.	Annual reassessments of the marketing authorisation	49
8.1.1.	Chenodeoxycholic acid – CHENODEOXYCHOLIC ACID LEADIANT (CAP) – EMA/S/0000340415	49
8.1.2.	Idursulfase – ELAPRASE (CAP) – EMA/S/0000339599	50
8.1.3.	Susoctocog alfa – OBIZUR (CAP) – EMA/S/0000324538	50
8.1.4.	Tabelecleucel – EBVALLO (CAP) – EMA/S/0000326533	50
8.1.5.	Zanamivir – DECTOVA (CAP) – EMA/S/0000339464.....	50
8.2.	Conditional renewals of the marketing authorisation	50

8.2.1.	Elranatamab – ELREXFIO (CAP) – EMA/R/0000347279	50
8.3.	Renewals of the marketing authorisation	51
8.3.1.	Avacopan – TAVNEOS (CAP) – EMA/R/0000340631	51
8.3.2.	Finerenone – KERENDIA (CAP) – EMA/R/0000340433	51
8.3.3.	Formoterol / Glycopyrronium bromide / Budesonide – RILTRAVA AEROSPHERE (CAP) – EMA/R/0000340519	51
8.3.4.	Lonapegsomatropin – SKYTROFA (CAP) – EMA/R/0000339532	51
8.3.5.	Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) – PREVENAR 20 (CAP) – EMA/R/0000340648	51
8.3.6.	Rivaroxaban – RIVAROXABAN VIATRIS (CAP) – EMA/R/0000327079.....	52
8.3.7.	Semaglutide – WEGOVY (CAP) – EMA/R/0000336288	52
8.3.8.	Somatrogon – NGENLA (CAP) – EMA/R/0000340629.....	52
8.3.9.	Tecovirimat – TECOVIRIMAT SIGA (CAP) – EMA/R/0000340615	52
8.3.10.	Tepotinib – TEPMETKO (CAP) – EMA/R/0000339701	52

9. Product related pharmacovigilance inspections 53

9.1.	List of planned pharmacovigilance inspections.....	53
9.2.	Ongoing or concluded pharmacovigilance inspections.....	53
9.3.	Others	53

10. Other safety issues for discussion requested by the Member States, CHMP or the EMA 53

10.1.1.	Botulinum toxin type A (NAP) - IE/H/xxxx/WS/380	53
---------	---	----

11. Scientific advice procedures 53

12. Organisational, regulatory and methodological matters 53

12.1.	Mandate and organisation of the PRAC.....	53
12.1.1.	Draft learning pharmacovigilance map and learning priorities for 2026-2028.....	53
12.1.2.	PRAC membership	54
12.1.3.	PRAC Rules of procedure - revision	54
12.1.4.	Nominated proxy	54
12.1.5.	Scientific Committee Meetings – alternating face-to-face and virtual meetings schedule for 2027	54
12.2.	Coordination with EMA Scientific Committees or CMDh-v	54
12.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	54
12.3.1.	Areas of collaboration between PRAC and Methodology Working Party (MWP)	54
12.4.	Cooperation within the EU regulatory network.....	54
12.5.	Cooperation with International Regulators.....	54
12.6.	Contacts of the PRAC with external parties and interaction with the Interested Parties to the Committee	54
12.7.	PRAC work plan	54
12.8.	Planning and reporting	55

12.8.1.	Marketing authorisation applications (MAA) forecast for 2026 – planning update dated Q2 2026	55
12.9.	Pharmacovigilance audits and inspections	55
12.9.1.	Pharmacovigilance systems and their quality systems	55
12.9.2.	Pharmacovigilance inspections	55
12.9.3.	Pharmacovigilance audits.....	55
12.10.	Periodic safety update reports (PSURs) & Union reference date (EURD) list	55
12.10.1.	Periodic safety update reports	55
12.10.2.	Granularity and Periodicity Advisory Group (GPAG)	55
12.10.3.	PSURs repository	55
12.10.4.	Union reference date list – consultation on the draft list	55
12.11.	Signal management	56
12.12.	Adverse drug reactions reporting and additional reporting	56
12.12.1.	Management and reporting of adverse reactions to medicinal products.....	56
12.12.2.	Additional monitoring	56
12.12.3.	List of products under additional monitoring – consultation on the draft list	56
12.13.	EudraVigilance database	56
12.13.1.	Activities related to the confirmation of full functionality	56
12.14.	Risk management plans and effectiveness of risk minimisations	56
12.14.1.	Risk management systems	56
12.14.2.	Tools, educational materials and effectiveness measurement of risk minimisations	56
12.15.	Post-authorisation safety studies (PASS)	56
12.15.1.	Post-authorisation Safety Studies – imposed PASS	56
12.15.2.	Post-authorisation Safety Studies – non-imposed PASS	56
12.16.	Community procedures.....	57
12.16.1.	Referral procedures for safety reasons	57
12.17.	Renewals, conditional renewals, annual reassessments.....	57
12.18.	Risk communication and transparency	57
12.18.1.	Public participation in pharmacovigilance	57
12.18.2.	Safety communication	57
12.19.	Continuous pharmacovigilance	57
12.19.1.	Incident management	57
12.20.	Impact of pharmacovigilance activities	57
12.20.1.	Reflection paper on digital support to risk minimisation measures (RMMs)	57
12.21.	Others	57
12.21.1.	Artificial Intelligence (AI) in pharmacovigilance guidance development.....	57
12.21.2.	DARWIN EU® study - Association between varicella vaccines (V), measles-mumps-rubella-varicella vaccines (MMRV), and encephalitis in paediatric recipients	58
12.21.3.	Good pharmacovigilance practice (GVP) – mid-year update 2026	58

12.21.4.	Guideline on good pharmacovigilance practices (GVP) Module III –Pharmacovigilance inspections (Rev 2).....	58
12.21.5.	Process for real-world interrogation network (DARWIN EU®) studies conducted for PRAC and real world evidence (RWE) – update	58
12.21.6.	Transition to IRIS for initial marketing authorisation applications and pre-submission activities - update	58

13.	Any other business	58
------------	---------------------------	-----------

14.	Explanatory notes	58
------------	--------------------------	-----------

1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PRAC plenary session to be held 06-09 July 2026. See July month 2026 PRAC minutes (to be published post September 2026 PRAC meeting).

1.2. Agenda of the meeting on 06-09 July 2026

Action: For adoption

1.3. Minutes of the previous meeting on 08-11 June 2026

Action: For adoption

2. EU referral procedures for safety reasons: urgent EU procedures

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

3. EU referral procedures for safety reasons: other EU referral procedures

3.1. Newly triggered procedure

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination procedures¹

None

3.5. Others

None

4. Signals assessment and prioritisation²

4.1. New signals detected from EU spontaneous reporting systems and/or other sources

4.1.1. Atogepant - AQUIPTA (CAP)

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: Signal of insomnia

Action: For adoption

EPITT 20291 – New signal

Lead Member State: LT

4.1.2. Atogepant - AQUIPTA (CAP); Erenumab – AIMOVIG (CAP); eptinezumab - VYEPTI (CAP); fremanezumab – AJOVY (CAP); galcanezumab – EMGALITY (CAP); rimegepant - VYDURA (CAP)

Applicant: AbbVie Deutschland GmbH & Co. KG (Aquirta), Eli Lilly Nederland B.V. (Emgality), H. Lundbeck A/S (Vyepti), Novartis Europharm Limited (Aimovig), Pfizer Europe MA EEIG (Vydura), TEVA GmbH (Ajovy)

PRAC Rapporteur: To be appointed

Scope: Signal of Raynaud's phenomenon

Action: For adoption

EPITT 20292 – New signal

Lead Member State: DK, FI, LT, NL

¹ Re-examination of PRAC recommendation under Article 32 of Directive 2001/83/EC

² Each signal refers to a substance or therapeutic class. The route of marketing authorisation is indicated in brackets (CAP for Centrally Authorised Products; NAP for Nationally Authorised Products including products authorised via Mutual Recognition Procedures and Decentralised Procedure). Product names are listed for reference Centrally Authorised Products (CAP) only. PRAC recommendations will specify the products concerned in case of any regulatory action required

4.1.3. Oseltamivir – TAMIFLU (CAP); zanamivir – DECTOVA (CAP)

Applicant(s): Roche Registration GmbH (Tamiflu); GlaxoSmithKline Trading Services Limited (Dectova)

PRAC Rapporteur: To be appointed

Scope: Signal of new information on the safety in patients critically ill with influenza

Action: For adoption

EPITT 20299 – New signal

Lead Member State: SE, FI

4.1.4. Sacituzumab govitecan - TRODELVY (CAP)

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Bianca Mulder

Scope: Signal of interstitial lung disease

Action: For adoption

EPITT 20290 – New signal

Lead Member State: NL

4.1.5. Selpercatinib – RETSEVMO (CAP)

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Signal of lymphangiectasia intestinal

Action: For adoption

EPITT 20289 – New signal

Lead Member State: NL

4.1.6. Sevoflurane (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of acute encephalopathy in patients carrying the mitochondrial DNA variant m.11232T>C

Action: For adoption

EPITT 20285 – New signal

Lead Member State: IE

4.2. Signals follow-up and prioritisation

4.2.1. Desogestrel (NAP), etonogestrel (NAP)

Applicant(s): various

PRAC Rapporteur: Karin Bolin

Scope: Signal of meningioma

Action: For adoption

EPITT 20167 – Follow-up to December 2025

4.2.2. Levonorgestrel intrauterine device 13.5 mg (Jaydess/Flere) (NAP)

Applicant(s): various

PRAC Rapporteur: Dennis Lex

Scope: Signal of increased risk of ectopic pregnancy

Action: For adoption

EPITT 20251 – Follow-up to March 2026

4.2.3. Venlafaxine (NAP)

Applicant(s): various

PRAC Rapporteur: Karin Bolin

Scope: Signal of cardiotoxicity

Action: For adoption

EPITT 20230 – Follow-up to December 2025

4.3. Variation procedure(s) resulting from signal evaluation

None

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Denecimig (CAP MAA) - EMEA/H/C/006344

Scope (pre D-180 phase): Prophylaxis of bleeding episodes in patients with haemophilia A

Action: For adoption

5.1.2. Gefurulumab (CAP MAA) - EMEA/H/C/006558

Scope (pre D-180 phase): Treatment of adult patients with generalised myasthenia gravis (gMG)

Action: For adoption

5.1.3. Navepegritide (CAP MAA) - EMEA/H/C/006627, Orphan

Scope (pre D-180 phase): Treatment of achondroplasia in children

Action: For adoption

5.1.4. Pegfilgrastim (CAP MAA) - EMEA/H/C/006937

Scope (pre D-60 phase): Treatment of neutropenia

Action: For adoption

5.1.5. Pertuzumab (CAP MAA) - EMEA/H/C/006844

Scope (pre D-180 phase): Treatment of breast cancer in adults

Action: For adoption

5.1.6. Povorcitinib (CAP MAA) - EMEA/H/C/006727

Scope (pre D-180 phase): Treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults

Action: For adoption

5.1.7. Relacorilant (CAP MAA) - EMEA/H/C/006731, Orphan

Scope (pre D-180 phase): Treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer

Action: For adoption

5.1.8. Riociguat (CAP MAA) - EMEA/H/C/006838

Scope (pre D-180 phase): Treatment of chronic thromboembolic pulmonary hypertension (CTEPH) in adults and treatment of pulmonary arterial hypertension (PAH) in adults and children from 6 years of age

Action: For adoption

5.1.9. Ruxolitinib (CAP MAA) - EMEA/H/C/006791

Scope (pre D-180 phase): Treatment of myelofibrosis (MF) in adults, treatment of polycythaemia vera (PV) in adults and treatment of graft versus host disease (GvHD) in

adults and children

Action: For adoption

5.1.10. Tofacitinib (CAP MAA) - EMEA/H/C/006698

Scope (pre D-180 phase): Treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis in adults, and juvenile idiopathic arthritis (JIA) in children from 2 years old

Action: For adoption

5.1.11. Zamtocabtagene autoleucel (CAP MAA) - EMEA/H/C/005495, PRIME, Orphan

ATMP

Scope (pre D-120 phase): Treatment of adults with large B-cell lymphoma

Action: For adoption

5.2. Medicines in the post-authorisation phase – PRAC-led procedures

5.2.1. Adalimumab – HUMIRA (CAP) – EMA/VR/0000342430

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Karin Bolin

Scope: Submission of an updated RMP version 18 in order to request an early closure of PAM MEA 075, associated with Humira adult ulcerative colitis registry, Study P11-282, resulting in the change of the study milestone dates in the risk management plan. This registry study is listed as an additional pharmacovigilance activity (category 3 study) in the RMP.

Action: For adoption

5.2.2. Cabozantinib – CABOMETYX (CAP); COMETRIQ (CAP) – EMA/VR/0000338165

Applicant: Ipsen Pharma

PRAC Rapporteur: Bianca Mulder

Scope: Submission of an updated RMP version 9.1 in order to propose the reclassification and removal of safety concerns.

Action: For adoption

5.2.3. Siponimod – MAYZENT (CAP) – EMA/VR/0000317924

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: A grouped application consisting of:

Type II (C.I.13): Submission of the final report from study CBAF312A2006 listed as a category 3 study in the RMP. This is a survey conducted among healthcare professionals and Multiple Sclerosis patients/caregivers in selected European countries plus Canada to evaluate the knowledge required for the safe use of Mayzent (siponimod). The RMP version 8.0 has also been submitted.

Type IB (C.I.11): Submission of an updated RMP version 8.0 in order to update the siponimod exposure data in accordance with the results of the drug-drug interaction study CBAF312A02101 in alignment with the EMA/VR/0000255116 procedure.

Action: For adoption

5.3. Medicines in the post-authorisation phase – CHMP-led procedures

5.3.1. Alpelisib – PIQRAY (CAP) – EMA/VR/0000317159

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication for PIQRAY in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following an endocrine-based regimen; based on the primary analysis (DCO 15-Oct-2024) from the Phase III Study CBYL719C2303 (C2303, EPIK-B5). This is a Phase III, randomized, double-blind, placebo-controlled study of alpelisib (BYL719) in combination with fulvestrant for men and postmenopausal women with HR-positive, HER2-negative advanced breast cancer with PIK3CA mutation, who progressed on or after aromatase inhibitor and a CDK4/6 inhibitor. As a consequence, sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.0 of the RMP has also been submitted.

Action: For adoption

5.3.2. Angiotensin II – GIAPREZA (CAP) – EMA/VR/0000343583

Applicant: Paion Deutschland GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Submission of the study protocol (CRH06) in order to modify the completion date of the Post-Authorization Efficacy Study (CRH06 / ARTISTRY) listed as an obligation in the Annex II. This is a Phase 4, randomized, double-blind, placebo-controlled, parallel group, multi-center post-authorization efficacy clinical trial of angiotensin II in adult patients with refractory vasodilatory shock and severe acute kidney injury. The Annex II and RMP version 2.1 are updated accordingly.

Action: For adoption

5.3.3. Asciminib – SCEMBLIX (CAP) – EMA/VR/0000342126

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Eva Jirsová

Scope: Update of section 4.4 of the SmPC in order to add a new warning on arterial occlusive events, based on a safety review. The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted.

Action: For adoption

5.3.4. [Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence – STRIMVELIS \(CAP\) – EMA/VR/0000347859](#)

Applicant: Fondazione Telethon Ets

PRAC Rapporteur: Liana Martirosyan

Scope: Quality

Action: For adoption

5.3.5. [Bictegravir / Emtricitabine / Tenofovir alafenamide – BIKTARVY \(CAP\) – EMA/VR/0000339784](#)

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final report from study GS-US-380-1474 listed as a category 3 study in the RMP. This is a Phase 2/3, Open-Label Study of the Pharmacokinetics, Safety, and Antiviral Activity of the GS-9883/Emtricitabine/Tenofovir Alafenamide (GS-9883/F/TAF) Fixed Dose Combination (FDC) in HIV-1 Infected Adolescents and Children. The RMP version 5.1 has also been submitted.

Action: For adoption

5.3.6. [Cabotegravir – VOCABRIA \(CAP\) – EMA/VR/0000332087](#)

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Update of sections 4.4, 4.6 and 5.2 of the SmPC in order to update information on pregnancy based on interim results from study HPTN 084/084-01; this is phase 3 double blind safety and efficacy study of long-acting injectable cabotegravir compared to daily oral TDF/FTC for pre-exposure prophylaxis in HIV-uninfected women – Pregnancy Safety and PK Interim Analysis; the Package Leaflet is updated accordingly. The RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template and to make typographical edits.

Action: For adoption

5.3.7. [Cabotegravir – APRETUDE \(CAP\) – EMA/VR/0000331993](#)

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Update of sections 4.6 and 5.2 of the SmPC in order to update information and recommendations on pregnancy, based on interim results from the open label extension (OLE) phase of the Phase 3 study HPTN 084 (study 201739) on the use of cabotegravir (CAB) for HIV-1 pre-exposure prophylaxis (PrEP) during pregnancy. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce updates to the information on excipients in alignment with the excipient guideline and to introduce minor editorial and formatting changes to the PI.

Action: For adoption

5.3.8. [Cemiplimab – LIBTAYO \(CAP\) – EMA/VR/0000347296](#)

Applicant: Regeneron Ireland Designated Activity Company

PRAC Rapporteur: Bianca Mulder

Scope: Update of sections 4.2 and 6.6 of the SmPC in order to apply the same posology approved for the adjuvant treatment of patients with cutaneous squamous cell carcinoma (CSCC) (350mg every 3 weeks (Q3W) for the first 12 weeks of treatment, followed by a switch to 700mg every 6 weeks (Q6W)) as an alternative dosing regimen for all approved indications. In addition, this variation includes an update to the infusion time (15 – 30 minutes) for the currently approved 350mg Q3W dosing regimen. This is based on pharmacokinetic and modelling data. The Package Leaflet has been updated accordingly. The RMP version 5.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the SmPC to include the E-number for the polysorbate 80 excipient (section 6.1) and to remove the nominal vial size (section 6.5) to allow flexibility for different vial sizes that may be sourced by approved manufacturers.

Action: For adoption

5.3.9. [Dimethyl fumarate – TECFIDERA \(CAP\) – EMA/VR/0000320745](#)

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Dennis Lex

Scope: Submission of the final study results from 109MS306 (CONNECT) Part 2 listed as a category 3 study in the RMP; this is a phase 3 efficacy and safety study of BG00012 in pediatric subjects with relapsing-remitting multiple sclerosis (RRMS). The primary objective of Part 2 is to evaluate the long-term safety of BG00012 in subjects who completed Week 96 in Part 1 of Study 109MS306. The secondary objective of Part 2 is to describe the long-term multiple sclerosis outcomes of BG00012 in subjects who completed Week 96 in Part 1 of Study 109MS306. The RMP version 17.1 has also been submitted.

Action: For adoption

5.3.10. [Dolutegravir / Lamivudine – DOVATO \(CAP\) – EMA/X/0000335457](#)

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: David Olsen

Scope: Extension application to introduce a new pharmaceutical form (dispersible tablet) associated with a new strength (5 mg/30 mg) grouped with an extension of indication type II variation (C.6.a) to include treatment of children weighing at least 20 kg for Dovato based on results from Study 207742 and Study 205861. Study 207742 is a randomised non-inferiority trial with nested PK to assess DTG/3TC fixed dose formulations for the maintenance of virological suppression in children with HIV infection aged 2 to <15 years old: Intensive PK Substudy; and study 205861 is a Phase 3b, open label, single arm study in Antiretroviral Therapy (ART)-naïve adolescents. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to update the PI in accordance with the latest EMA excipients guideline.

Action: For adoption

5.3.11. Eravacycline – XERAVA (CAP) – EMA/VR/0000343900

Applicant: Paion Pharma GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Update of section 5.1 of the SmPC in order to update the list of pathogens susceptible to eravacycline, based on the final results from study NC-IHMA-2018-01, listed as a category 3 study in the RMP; this is a surveillance study of the activity of eravacycline against bacteria collected from hospitals in Asia / Pacific, Europe and the USA from 2018 to 2022. The RMP version 4.2 has also been submitted.

Action: For adoption

5.3.12. Etranacogene dezaparovec – HEMGENIX (CAP) – EMA/VR/0000347644

Applicant: CSL Behring GmbH

PRAC Rapporteur: Bianca Mulder

Scope: A grouped application consisting of:

Type II (C.9.c) to update the protocol and Statistical Analysis Plan (SAP) of Study CSL222_4001, listed as a Specific Obligation in the Annex II of the Product Information. CSL222_4001 is an observational, post-authorisation, long-term follow-up study designed to evaluate the effectiveness and safety of HEMGENIX in the commercial setting. The Annex II and the RMP (version 1.1) are updated accordingly.

Type IB (C.9.b) to request a one-year extension to the due date of Specific Obligation 3 (SOB3) under Annex II.E of the conditional marketing authorisation.

Action: For adoption

5.3.13. Evolocumab – REPATHA (CAP) – EMA/VR/0000322435

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to extend the indication for REPATHA to include adults at high risk for a first cardiovascular event, based on the final results from study 20170625 (VESALIUS); this is a Phase 3, double-blind, randomized, placebo-controlled, multicenter study to evaluate the impact of evolocumab on major cardiovascular events in patients at high cardiovascular risk without prior myocardial infarction or stroke. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, some typographical errors were corrected, and the PI is brought in line with the latest QRD template version.

Action: For adoption

5.3.14. Faricimab – VABYSMO (CAP) – EMA/VR/0000308736

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Update of sections 4.4 and 5.1 of the SmPC in order to update safety information, based on final results from study GR42691 (AVONELLE-X) listed as a category 3 study in the RMP. This was a multicenter, open-label extension study to evaluate the long-term safety and tolerability of faricimab in patients with neovascular Age-related Macular Degeneration (nAMD). The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to introduce administrative and editorial changes to the PI, including to the Annex II, Labelling and to the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.15. Fedratinib – INREBIC (CAP) – EMA/VR/0000324950

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Sonja Radowan

Scope: A grouped application consisting of:

C.4. Update of sections 4.4, 4.8, and 5.1 of the SmPC in order to update clinical pharmacology, efficacy and safety information based on final results from study FEDR MF 002 listed as a category 3 study in the RMP; this is a phase 3, multicenter, open-label, randomized study to evaluate the efficacy and safety of fedratinib compared to best available therapy in subjects with dipss-intermediate or high-risk primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis and previously treated with ruxolitinib; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted.

C.3. Update of section 4.8 of the SmPC in order to add subdural hematoma to the list of adverse drug reactions (ADRs) following recommendation of PSUSA PSUSA/00010909/202508.

Action: For adoption

5.3.16. Glycopyrronium – SIALANAR (CAP) – EMA/X/0000287532

Applicant: Proveca Pharma Limited

PRAC Rapporteur: Zane Neikena

Scope: Extension application to introduce a new pharmaceutical form associated with two new strengths (0.68 mg and 1.36 mg orodispersible tablets).

Action: For adoption

5.3.17. Insulin icodec / Semaglutide – KYINSU (CAP) – EMA/VR/0000322527

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise for KYINSU, based on results from the Phase 3b study NN1535-4988 (COMBINE 4); this is a 40-week study comparing the efficacy and safety of once weekly IcoSema and daily insulin glargine 100 units/mL in participants with type 2 diabetes inadequately controlled on oral anti-diabetic drugs. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.3.18. Lacosamide – LACOSAMIDE UCB (CAP); VIMPAT (CAP) – EMA/VR/0000321459

Applicant: UCB Pharma

PRAC Rapporteur: Karin Bolin

Scope: Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update clinical information based on final results from study SP0968 and study EP0223. SP0968 was a phase 2/3, multicenter, open-label, randomized, active comparator study that evaluated the PK, efficacy, safety, and tolerability of lacosamide in neonatal study participants with repeated electroencephalographic neonatal seizures compared with an Active Comparator chosen based on standard of care per the local practice and treatment guidelines. EP0223 is a comparative study on long-term neurodevelopmental outcomes in neonates treated with lacosamide versus other antiseizure medications for neonatal seizures. The RMP version 18.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to implement corrections in some local languages in both Vimpat and Lacosamide UCB Product Information.

Action: For adoption

5.3.19. Mavacamten – CAMZYOS (CAP) – EMA/VR/0000343906

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Submission of the final report from study CV0271148, listed as a category 3 study in the RMP. This is a meta-analysis to assess cardiovascular safety of mavacamten. RMP version 8.0 has also been submitted.

Action: For adoption

5.3.20. Nusinersen – SPINRAZA (CAP) – EMA/VR/0000343403

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Karin Bolin

Scope: A grouped application to update sections 4.8, 5.1 and 5.2 of the SmPC in order to update clinical safety, efficacy, and immunogenicity information based on the results from study 232SM201 (NURTURE), listed as a PAES in the Annex II, and study 232SM404 (RESPOND). NURTURE is a Phase 2 open-label study to assess the efficacy, safety, tolerability, and pharmacokinetics of multiple doses of nusinersen delivered intrathecally to subjects with genetically diagnosed and presymptomatic spinal muscular atrophy, while RESPOND is a Phase 4 study of nusinersen among patients with spinal muscular atrophy who received onasemnogene abeparvovec. The Annex II is updated accordingly. The RMP version 14.1 has also been submitted.

Action: For adoption

5.3.21. Osimertinib – TAGRISSO (CAP) – EMA/VR/0000340013

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Update of section 4.4 of the SmPC in order to update safety data based on post-marketing experience and literature. The Package Leaflet is updated accordingly. The RMP version 18.1 has also been submitted.

Action: For adoption

5.3.22. Pandemic influenza vaccine (H5N1) (live attenuated, nasal) – PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) – EMA/VR/0000321324

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Extension of indication to remove the upper age limit from the indication for Pandemic influenza vaccine (H5N1) (live, nasal), based on efficacy and safety data previously submitted in the Marketing Authorisation Application (MAA). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, and 5.3 of the SmPC are updated. The Annex II and the Package Leaflet are updated in accordance. Version 2.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes throughout the PI and update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.23. Pembrolizumab – KEYTRUDA (CAP) – EMA/VR/0000340550

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include, in combination with chemotherapy with or without radiation, the adjuvant treatment of mismatch repair deficient (dMMR) endometrial cancer in adults who are at high risk of recurrence, for KEYTRUDA, based on results from the study KEYNOTE-B21; this is a phase 3, randomized, double-blind study of pembrolizumab versus placebo in combination with adjuvant chemotherapy with or without radiotherapy for the treatment of newly diagnosed high risk endometrial cancer after surgery with curative intent (KEYNOTE-B21 / ENGOT-en11 / GOG 3053). As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 55.1 of the RMP has also been submitted.

Action: For adoption

5.3.24. Pemigatinib – PEMAZYRE (CAP) – EMA/VR/0000343983

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Bianca Mulder

Scope: A grouped application consisting of two Type II Variations, as follows:

C.4: Update of sections 4.4, 4.5, and 4.8 of the SmPC in order to update clinical information based on final results from study INCB 54828-302 (FIGHT-302), listed as a specific obligation in the Annex II; this is a phase 3, open-label, randomized, active-controlled, multicenter study comparing the efficacy and safety of pemigatinib vs. gemcitabine plus cisplatin chemotherapy in adults with unresectable or metastatic cholangiocarcinoma with fibroblast growth factor receptor 2 (FGFR2) rearrangement. The Annex II and Package Leaflet are updated accordingly.

C.9: Submission of the final report from study CIBI375A201, listed as a specific obligation in the Annex II of the Product Information. This is a phase 2 open-label, single-arm, multicenter study evaluating the efficacy and safety of pemigatinib in subjects with surgically unresectable and locally advanced, recurrent or metastatic cholangiocarcinoma with FGFR2 fusion or rearrangement who have failed at least one prior systemic therapy. The Annex II is updated accordingly.

The RMP version 4.2 has also been submitted.

Action: For adoption

5.3.25. Respiratory syncytial virus vaccine (bivalent, recombinant) – ABRYSV0 (CAP) – EMA/VR/0000343072

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on results from Phase 3 studies C3671032 and C3671013. The RMP version 2.1 has also been submitted.

Action: For adoption

5.3.26. Sacituzumab govitecan – TRODELVY (CAP) – EMA/VR/0000320818

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include Trodelvy, in combination with pembrolizumab, for the treatment of adult patients with unresectable locally advanced or metastatic TNBC who have not received prior systemic therapy for metastatic disease and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10 , based on results from study GS-US-592-6173 (ASCENT-04), which is a phase 3 study of sacituzumab govitecan (IMMU-132) and Pembrolizumab versus treatment of physician's choice and Pembrolizumab in patients with previously untreated, locally advanced inoperable or metastatic triple-negative breast cancer, whose tumors express PD-L1. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.2 of the RMP has also been submitted.

Action: For adoption

5.3.27. Secukinumab – COSENTYX (CAP) – EMA/VR/0000340032

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Extension of indication to include treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents 12 years and older with an inadequate response to conventional systemic HS therapy for COSENTYX, based on modeling and extrapolation of existing data. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI, including to the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.28. Semaglutide – WEGOVY (CAP) – EMA/VR/0000327359

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Karin Bolin

Scope: Update of sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to reflect clinical results related to adults with overweight/obesity and metabolic dysfunction-associated steatohepatitis (MASH) based on interim results from phase 3a clinical study NN9931-4553 (ESSENCE) as well as three additional clinical trials NN9931-4381, NN9931-4296 and NN9931-4492 in adults with metabolic dysfunction-associated steatotic liver disease and/or MASH; supportive non-clinical results have also been submitted. The Package Leaflet is updated accordingly. The RMP version 10.2 has also been submitted.

Action: For adoption

5.3.29. Tafasitamab – MINJUVI (CAP) – EMA/VR/0000339938

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Extension of indication for MINJUVI, in combination with lenalidomide and rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) to include treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL), or high-grade B-cell lymphoma (HGBL) who have high-intermediate or high-risk disease (International Prognostic Index score of 3 or greater), based on results from phase 3 study MOR208C310 (frontMIND) and results from phase 1b study MOR208C107. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is also updated in accordance. A revised RMP version 4.1 is also being submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

Action: For adoption

5.3.30. Talquetamab – TALVEY (CAP) – EMA/VR/0000339914

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Extension of indication for TALVEY in combination with daratumumab and pomalidomide, or in combination with daratumumab, to include treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior therapy based on interim analysis from Phase 3 study MonumenTAL-3 (64407564MMY3002) and data from the supportive Phase 1b study TriMM-2 (64407564MMY1002). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated accordingly. The updated RMP version 4.1 has also been submitted. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. In addition, the MAH took the opportunity to update Annex II and to update the list of local representatives in the Package Leaflet. Furthermore, as part of the application the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.31. Tucatinib – TUKYSA (CAP) – EMA/VR/0000341660

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.4, and 4.8 of the SmPC in order to update information concerning hepatotoxicity based on the review of aggregate data from multiple studies, including randomized, controlled studies (HER2CLIMB-05, HER2CLIMB, and HER2CLIMB-02), and study MK-7119-001. The RMP version 4.0 has also been submitted.

Action: For adoption

5.3.32. Upadacitinib – RINVOQ (CAP) – EMA/X/0000304823

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength and change of pharmacokinetics (1 mg/ml oral solution) grouped with an extension of indication (C.I.6.a) to include the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older based on clinical data and results from clinical phase 1 study (study M15-340). As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC have been updated. The Package Leaflet has been updated accordingly. Version 17 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II.

Action: For adoption

5.3.33. Vamorolone – AGAMREE (CAP) – EMA/VR/0000343140

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Submission of updated comprehensive safety data from studies VBP15-006, SNT-I-VAM-024, SNT-I-VAM-025, and SNT-I-VAM-026, expanded-access programs, compassionate use and named patient programs as well as data from ongoing clinical trial SNT-IV-VAM-011 and post-marketing data. The RMP version 3.0 has also been submitted.

Action: For adoption

5.3.34. Vedolizumab – ENTYVIO (CAP) – EMA/VR/0000340504

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application consisting of:

Type II - C.6.a: Extension of indication to include treatment of ulcerative colitis (UC) and of Crohn's disease (CD) in the paediatric population from 2 to less than 18 years for Entyvio 300 mg powder for concentrate for solution for infusion (intravenous, IV), based on final results from studies MLN0002-2005, vedolizumab-2005 and MLN002-3024 and interim results from studies MLN0002-3025 and MLN0002-3029. These are phase 2 and phase 3 interventional studies to assess the pharmacokinetics, efficacy and safety of vedolizumab intravenous in paediatric UC and CD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.3 and 6.6 of the IV SmPC and Sections 4.2 and 5.1 of the subcutaneous (SC) product SmPC are updated. The IV Package Leaflet (PL) is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the PI, and to update the list of local representatives in the PL. Version 10.0 of the RMP has also been submitted

Type II – C.4: To update section 6.6. of the SmPC to add a 50 mL saline bag for dilution prior to administration for the finished product. The PL has been updated accordingly.

Action: For adoption

5.3.35. Vosoritide – VOXZOGO (CAP) – EMA/VR/0000343152

Applicant: Biomarín International Limited

PRAC Rapporteur: Zane Neikena

Scope: Update of section 4.8 of the SmPC in order to add 'femur fracture' to the list of adverse drug reactions (ADRs) with frequency 'common' based on post-marketing data. The Package Leaflet is updated in accordance. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to update the PI in accordance with the latest EMA excipients guideline.

Action: For adoption

6. Periodic safety update reports (PSURs)

6.1. PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) only

6.1.1. Acridinium / Formoterol fumarate dihydrate – BRIMICA GENUAIR (CAP); DUAKLIR GENUAIR (CAP) – EMA/PSUR/0000336119

Applicant: Covis Pharma Europe B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010307/202511)

Action: For adoption

6.1.2. Adagrasib – KRAZATI (CAP) – EMA/PSUR/0000336084

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00000214/202512)

Action: For adoption

6.1.3. Aflibercept – AFIVEG (CAP); AFQLIR (CAP); AHZANTIVE (CAP); BAIAMA (CAP); EIYZEY (CAP); EYDENZELT (CAP); EYLEA (CAP); EYLUXVI (CAP); MYNZEPLI (CAP); OPUVIZ (CAP); PAVBLU (CAP); VGENFLI (CAP); YESAFILI (CAP) – EMA/PSUR/0000336116

Applicants: Biolitec Pharma Limited, Bayer AG, Advanz Pharma Limited, ZAKLADY FARMACEUTYCZNE POLPHARMA S.A., Amgen Technology (Ireland) Unlimited Company, Celltrion Healthcare Hungary Kft., Formycon AG, Samsung Bioepis NL B.V., Sandoz GmbH, STADA Arzneimittel AG, Biosimilar Collaborations Ireland Limited

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00010020/202511)

Action: For adoption

6.1.4. [Arpraziquantel – ARPRAZIUANTEL \(Art 58\) – EMA/PSUR/0000333585](#)

Applicant: Merck Europe B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUV arpraziquantel)

Action: For adoption

6.1.5. [Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence – STRIMVELIS \(CAP\) – EMA/PSUR/0000336165](#)

Applicant: Fondazione Telethon Ets

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010505/202511)

Action: For adoption

6.1.6. [Benralizumab – FASENRA \(CAP\) – EMA/PSUR/0000336112](#)

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010661/202511)

Action: For adoption

6.1.7. [Blinatumomab – BLINCYTO \(CAP\) – EMA/PSUR/0000336108](#)

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00010460/202512)

Action: For adoption

6.1.8. [Budesonide – KINPEYGO \(CAP\) – EMA/PSUR/0000336136](#)

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011007/202512)

Action: For adoption

6.1.9. [Concentrate of proteolytic enzymes enriched in bromelain – NEXOBRID \(CAP\) – EMA/PSUR/0000336099](#)

Applicant: MediWound Germany GmbH

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010028/202512)

Action: For adoption

6.1.10. [COVID-19 vaccine \(recombinant, adjuvanted\) – NUVAXOVID \(CAP\) – EMA/PSUR/0000336124](#)

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010972/202512)

Action: For adoption

6.1.11. [Datopotamab deruxtecan – DATROWAY \(CAP\) – EMA/PSUR/0000336154](#)

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00011129/202512)

Action: For adoption

6.1.12. [Deutivacaftor / Tezacaftor / Vanzacaftor – ALYFTREK \(CAP\) – EMA/PSUR/0000336139](#)

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011146/202512)

Action: For adoption

6.1.13. [Efgartigimod alfa – VYVGART \(CAP\) – EMA/PSUR/0000336133](#)

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00011014/202512)

Action: For adoption

6.1.14. Elacestrant – ORSERDU (CAP) – EMA/PSUR/0000336096

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000120/202512)

Action: For adoption

6.1.15. Elafibranor – IQIRVO (CAP) – EMA/PSUR/0000336148

Applicant: Ipsen Pharma

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00011092/202512)

Action: For adoption

6.1.16. Enfortumab vedotin – PADCEV (CAP) – EMA/PSUR/0000336134

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00010989/202512)

Action: For adoption

6.1.17. Entrectinib – ROZLYTREK (CAP) – EMA/PSUR/0000336153

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010874/202512)

Action: For adoption

6.1.18. Eplontersen – WAINZUA (CAP) – EMA/PSUR/0000336131

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011120/202512)

Action: For adoption

6.1.19. Ferric citrate coordination complex – XOANACYL (CAP) – EMA/PSUR/0000336132

Applicant: Averoa

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00011140/202512)

Action: For adoption

6.1.20. Flortaucipir (18F) – TAUVID (CAP) – EMA/PSUR/0000336149

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011073/202511)

Action: For adoption

6.1.21. Givinostat – DUVYZAT (CAP) – EMA/PSUR/0000336164

Applicant: Italfarmaco S.p.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011141/202512)

Action: For adoption

6.1.22. Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) – CERVARIX (CAP) – EMA/PSUR/0000336113

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00009175/202511)

Action: For adoption

6.1.23. Hydroxocobalamin – CYANOKIT (CAP) – EMA/PSUR/0000336100

Applicant: Serb

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00010228/202511)

Action: For adoption

6.1.24. Ibrutinib – IMBRUVICA (CAP) – EMA/PSUR/0000336107

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00010301/202511)

Action: For adoption

6.1.25. Imetelstat – RYTELO (CAP) – EMA/PSUR/0000336130

Applicant: Geron Netherlands B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011117/202512)

Action: For adoption

6.1.26. Inclisiran – LEQVIO (CAP) – EMA/PSUR/0000336155

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010904/202512)

Action: For adoption

6.1.27. Inotuzumab ozogamicin – BESPONSA (CAP) – EMA/PSUR/0000336115

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010659/202512)

Action: For adoption

6.1.28. Iptacopan – FABHALTA (CAP) – EMA/PSUR/0000336141

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure (PSUSA/00011054/202512)

Action: For adoption

6.1.29. Ixazomib – NINLARO (CAP) – EMA/PSUR/0000336109

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00010535/202511)

Action: For adoption

6.1.30. Levodopa – INBRIJA (CAP) – EMA/PSUR/0000336140

Applicant: Merz Therapeutics GmbH

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00107800/202512)

Action: For adoption

6.1.31. Mosunetuzumab – LUNSUMIO (CAP) – EMA/PSUR/0000336142

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00010999/202512)

Action: For adoption

6.1.32. Nirmatrelvir / Ritonavir – PAXLOVID (CAP) – EMA/PSUR/0000336147

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010984/202512)

Action: For adoption

6.1.33. Octreotide – OCZYESA (CAP) – EMA/PSUR/0000336143

Applicant: Camurus AB

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00011036/202512)

Action: For adoption

6.1.34. Olezarsen – TRYNGOLZA (CAP) – EMA/PSUR/0000336151

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00011155/202512)

Action: For adoption

6.1.35. Padeliporfin – TOOKAD (CAP) – EMA/PSUR/0000336122

Applicant: Steba Biotech S.A.

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00010654/202511)

Action: For adoption

6.1.36. Pegvisomant – SOMAVERT (CAP) – EMA/PSUR/0000336093

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00002328/202511)

Action: For adoption

6.1.37. Pegzilarginase – LOARGYS (CAP) – EMA/PSUR/0000336083

Applicant: Immedica Pharma AB

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00000222/202512)

Action: For adoption

6.1.38. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) – PREVENAR 20 (CAP) – EMA/PSUR/0000336138

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010981/202512)

Action: For adoption

6.1.39. Pneumococcal polysaccharide conjugate vaccine (21-valent) – CAPVAXIVE (CAP) – EMA/PSUR/0000336152

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00011121/202512)

Action: For adoption

6.1.40. Prasterone – INTRAROSA (CAP) – EMA/PSUR/0000336121

Applicant: Endoceutics S.A.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010672/202511)

Action: For adoption

6.1.41. Respiratory syncytial virus mRNA vaccine (nucleoside modified) – MRESVIA (CAP) – EMA/PSUR/0000336146

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00011075/202511)

Action: For adoption

6.1.42. Ritlecitinib – LITFULO (CAP) – EMA/PSUR/0000336091

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000133/202512)

Action: For adoption

Oral explanation

6.1.43. Roxadustat – EVRENZO (CAP) – EMA/PSUR/0000336126

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Jana Pecherova

Scope: Evaluation of a PSUSA procedure (PSUSA/00010955/202512)

Action: For adoption

6.1.44. Sepiapterin – SEPHIENCE (CAP) – EMA/PSUR/0000336127

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011145/202512)

Action: For adoption

6.1.45. Sipavibart – KAVIGALE (CAP) – EMA/PSUR/0000336123

Applicant: AstraZeneca AB

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00011113/202512)

Action: For adoption

6.1.46. Sugemalimab – CEJEMLY (CAP) – EMA/PSUR/0000336144

Applicant: Cstone Pharmaceuticals Ireland Limited

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00011080/202512)

Action: For adoption

6.1.47. [Susoctocog alfa – OBIZUR \(CAP\) – EMA/PSUR/0000336105](#)

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010458/202511)

Action: For adoption

6.1.48. [Tabelecleucel – EBVALLO \(CAP\) – EMA/PSUR/0000336145](#)

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00011028/202512)

Action: For adoption

6.1.49. [Tezepelumab – TEZSPIRE \(CAP\) – EMA/PSUR/0000336135](#)

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00011015/202512)

Action: For adoption

6.1.50. [Tirbanibulin – KLISYRI \(CAP\) – EMA/PSUR/0000336129](#)

Applicant: Almirall S.A.

PRAC Rapporteur: Jana Pecherova

Scope: Evaluation of a PSUSA procedure (PSUSA/00010943/202512)

Action: For adoption

6.1.51. [Tislelizumab – TEVIMBRA \(CAP\) – EMA/PSUR/0000336087](#)

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000136/202512)

Action: For adoption

6.1.52. [Toripalimab – LOQTORZI \(CAP\) – EMA/PSUR/0000336150](#)

Applicant: Topalliance Biosciences Europe Limited

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00011094/202512)

Action: For adoption

6.1.53. Tralokinumab – ADTRALZA (CAP) – EMA/PSUR/0000336125

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010937/202512)

Action: For adoption

6.1.54. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/PSUR/0000336128

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010894/202512)

Action: For adoption

6.1.55. Ublituximab – BRIUMVI (CAP) – EMA/PSUR/0000336163

Applicant: Neuraxpharm Pharmaceuticals S.L.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000045/202512)

Action: For adoption

6.1.56. Vadadustat – VAFSEO (CAP) – EMA/PSUR/0000336137

Applicant: Medice Arzneimittel Puetter GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00011050/202512)

Action: For adoption

6.2. PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) and nationally authorised products (NAPs)

6.2.1. Clopidogrel – CLOPIDOGREL ZENTIVA (CAP); ISCOVER (CAP); PLAVIX (CAP); Clopidogrel / Acetylsalicylic acid – DUOPLAVIN (CAP); NAP – EMA/PSUR/0000336095

Applicants: Sanofi Winthrop Industrie, Zentiva k.s., various

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00000820/202511)

Action: For adoption

6.2.2. [Edotreotide – SOMAKIT TOC \(CAP\); NAP – EMA/PSUR/0000336114](#)

Applicants: Advanced Accelerator Applications, various

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00010552/202512)

Action: For adoption

6.3. **PSUR single assessment (PSUSA) procedures including nationally authorised products (NAPs) only**

6.3.1. [Apomorphine – EMA/PSUR/0000336097](#)

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000227/202511)

Action: For adoption

6.3.2. [Ascorbic acid / rutoside, ascorbic acid / rutoside / alfatocopherol – EMA/PSUR/0000336104](#)

Applicants: various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010504/202512)

Action: For adoption

6.3.3. [Benazepril – EMA/PSUR/0000336080](#)

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000313/202511)

Action: For adoption

6.3.4. [Benzalkonium / benzocaine / tyrothricin – EMA/PSUR/0000336111](#)

Applicants: various

PRAC Lead: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00003070/202512)

Action: For adoption

6.3.5. [Benzalkonium chloride / isopropyl myristate / paraffin liquid, benzalkonium chloride / chlorhexidine / isopropyl myristate / paraffin liquid – EMA/PSUR/0000336117](#)

Applicants: various

PRAC Lead: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00010640/202512)

Action: For adoption

6.3.6. [Biclotymol / enoxolone / muramidase hydrochloride – EMA/PSUR/0000336089](#)

Applicants: various

PRAC Lead: Guðrún Stefánsdóttir

Scope: Evaluation of a PSUSA procedure (PSUSA/00000409/202512)

Action: For adoption

6.3.7. [Brotizolam – EMA/PSUR/0000336092](#)

Applicants: various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00000444/202512)

Action: For adoption

6.3.8. [Caffeine / dimenhydrinate, dimenhydrinate – EMA/PSUR/0000336086](#)

Applicants: various

PRAC Lead: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00001088/202512)

Action: For adoption

6.3.9. [Caffeine / ergotamine – EMA/PSUR/0000336078](#)

Applicants: various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00000485/202511)

Action: For adoption

6.3.10. Caffeine / paracetamol / propyphenazone, paracetamol / propyphenazone –
EMA/PSUR/0000336094

Applicants: various

PRAC Lead: Roxana Stefania Udrescu

Scope: Evaluation of a PSUSA procedure (PSUSA/00002298/202512)

Action: For adoption

6.3.11. Carbaethopendecinium bromide / trimecaine hydrochloride –
EMA/PSUR/0000336106

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00003041/202512)

Action: For adoption

6.3.12. Chlorhexidine gluconate / isopropyl alcohol (covers other synonymous terms such
as 2-propanol) – EMA/PSUR/0000336079

Applicants: various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00000669/202512)

Action: For adoption

6.3.13. Choline salicylate – EMA/PSUR/0000336077

Applicants: various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000732/202512)

Action: For adoption

6.3.14. Clomifene – EMA/PSUR/0000336082

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00000810/202512)

Action: For adoption

6.3.15. Dienogest – EMA/PSUR/0000336102

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00003167/202512)

Action: For adoption

6.3.16. [Idarubicin – EMA/PSUR/0000336098](#)

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00001720/202511)

Action: For adoption

6.3.17. [Indapamide – EMA/PSUR/0000336085](#)

Applicants: various

PRAC Lead: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00001731/202511)

Action: For adoption

6.3.18. [Naltrexone – EMA/PSUR/0000336088](#)

Applicants: various

PRAC Lead: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00002117/202511)

Action: For adoption

6.3.19. [Pancuronium – EMA/PSUR/0000336090](#)

Applicants: various

PRAC Lead: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00002275/202512)

Action: For adoption

6.3.20. [Phenylephrine / tropicamide – EMA/PSUR/0000336103](#)

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00010430/202511)

Action: For adoption

6.3.21. Sultamicillin – EMA/PSUR/0000336101

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00002829/202511)

Action: For adoption

6.3.22. Vecuronium bromide – EMA/PSUR/0000336110

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00003102/202511)

Action: For adoption

6.3.23. Yellow fever vaccine (live) – EMA/PSUR/0000337795

Applicants: various

PRAC Lead: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00003135/202512)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Rotavirus vaccine, live – ROTARIX (CAP) – EMA/PAM/0000343686

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Jean-Michel Dogné

Scope: LEG - a legally binding cumulative safety reviews of all serious cases of rotavirus gastroenteritis in children without immune deficiency, of vomiting and of immune thrombocytopenic purpura (ITP) requested by PRAC further to the assessment of the latest PSUR.

Considering the findings an update of the product information and/or the risk management plan could be warranted.

Action: For adoption

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Zilucoplan – ZILBRYSQ (CAP) – EMA/VR/0000343399

Applicant: UCB Pharma

PRAC Rapporteur: Karin Erneholm

Scope: Update of Annex IID of the PI in order to implement the outcome of PSUR procedure, PSUSA/00000169/202509, recommending to remove the Controlled Access Program linked to the safety concern 'meningococcal infection' from the RMP. The RMP version v1.1 has also been submitted along with updated educational materials, as per PRAC recommendation.

Action: For adoption

6.6. Expedited summary safety reviews³

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)⁴

7.1.1. Beremagene geperpavec – VYJUVEK (CAP) – EMA/PASS/0000287685

Applicant: Krystal Biotech Netherlands B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: PASS protocol [107n]: A prospective, non-interventional, multi-country study to confirm the long-term safety profile, including in paediatric patients less than 6 months of age, of B-VEC for the treatment of DEB wounds in a real-life clinical setting.

Action: For adoption

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)⁵

7.2.1. Cabotegravir – APRETUDE (CAP) – EMA/PAM/0000343607

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Substantial amendments to the protocol of the following Apretude PAM: "CAB LA PrEP Cohort: Prospective Cohort Study to Assess Adherence and Effectiveness of, and Monitor for Hepatotoxicity and Resistance to, Cabotegravir for Pre-Exposure Prophylaxis in Europe" (PASS Study, RMP cat 3).

Action: For adoption

³ Submission of expedited summary safety reports for review in addition to the requirements for submission of PSUR(s) falling within the pandemic period and requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC

⁴ In accordance with Article 107n of Directive 2001/83/EC

⁵ In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

7.2.2. Chikungunya vaccine (live) – IXCHIQ (CAP) – EMA/PAM/0000341603

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of the protocols for the post-authorisation safety studies VLA1553-403 (version 6.0) and VLA1553-406 (version 6.0) which are category 3 studies in the RMP. VLA1553-403 is an observational study to evaluate the safety of VLA1553 in pregnant women exposed to the vaccine in Brazil. VLA1553-406 is a prospective safety cohort study.

Action: For adoption

7.2.3. Cladribine – MAVENCLAD (CAP) – EMA/PAM/0000319565

Applicant: Merck Europe B.V.

PRAC Rapporteur: Carla Torre

Scope: Protocol amendment for PASS MS 700568-0002: Long-term prospective, observational cohort study evaluating the safety profile, in terms of incidence of adverse events of special interest, in patients with highly active relapsing multiple sclerosis (RMS) newly started on oral cladribine (CLARION)

Action: For adoption

7.2.4. Inebilizumab – UPLIZNA (CAP) – EMA/PAM/0000325493

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Protocol amendment submission of PASS Cat.3 Study A real-world observational study of treatment patterns and outcomes for patients with neuromyelitis optica spectrum disorders (NMOSDs) and immunoglobulin G4-related disease (IgG4-RD) treated with inebilizumab (UPLIZNA) in Europe

Action: For adoption

7.2.5. Levacetylleucine – AQNEURSA (CAP) – EMA/PAM/0000340768

Applicant: Intrabio Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: Protocol submission for Post-authorisation, non-interventional study using existing International Niemann Pick Disease Registry (INPDR) as data source

Action: For adoption

7.2.6. Maribavir – LIVTENCITY (CAP) – EMA/PAM/0000343616

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Adam Przybylkowski

Scope: Submission of a second protocol amendment for Study TAK-620-4007, a Retrospective chart review of safety outcomes associated with use of maribavir in patients with post-transplant refractory cytomegalovirus (CMV) infection and comorbid severe chronic kidney disease (CKD) or comorbid end-stage renal disease (ESRD), including patients on peritoneal dialysis or hemodialysis.

Action: For adoption

7.2.7. Rimegepant – VYDURA (CAP) – EMA/PAM/0000343596

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Erneholm

Scope: Fifth Annual Interim Report, Updated Protocol and SAP for Pfizer Study C4951006

Additional Survey Study Report for C4951006

Action: For adoption

7.3. Results of PASS imposed in the marketing authorisation(s)⁶

7.3.1. Blinatumomab – BLINCYTO (CAP) – EMA/PASS/0000262863

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Veronika Macurova

Scope: PASS results [107q]: Final study report for an observational study of blinatumomab safety and effectiveness, utilisation, and treatment practices

Action: For adoption

7.3.2. Sodium valproate (NAP) – EMA/PASS/0000287665

Applicants: various

PRAC Rapporteur: Liana Martirosyan

Scope: valproate PASS results [107q]: Final study results for Drug Utilisation Study extension of valproate and related substances, in Europe, using databases.

Action: For adoption

Oral explanation

⁶ In accordance with Article 107p-q of Directive 2001/83/EC

7.4. Results of PASS imposed and non-imposed in the marketing authorisation(s)⁷

7.4.1. Brexpiprazole – RXULTI (CAP) – EMA/VR/0000340645

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Miroslava Gocova

Scope: Submission of an updated RMP version 3.0 in order to remove National Pregnancy Registry for Atypical Antipsychotics (NPRAA) listed as Category 3 study from the RMP.

Action: For adoption

7.4.2. Eslicarbazepine acetate – ZEBINIX (CAP) – EMA/VR/0000332409

Applicant: Bial Portela & Ca S.A.

PRAC Rapporteur: Dennis Lex

Scope: Submission of the final report from the post authorisations safety study EURAP (BIA-2093-402) listed as a category 3 study in the RMP. This is an international, prospective observational registry designed to assess the risks associated with antiepileptic drug exposure during pregnancy. The updated RMP version 23.0 has also been submitted. Risk information has been updated based on clinical evidence, including clinical trials and post-marketing data, together with a comprehensive review of the published literature.

Action: For adoption

7.4.3. Nirmatrelvir / Ritonavir – PAXLOVID (CAP) – EMA/VR/0000339731

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Dennis Lex

Scope: Submission of the final report from study C4671037, listed as a category 3 study in the RMP. This is a non-interventional post-authorisation safety study to assess the safety of Paxlovid in pregnant women.

Action: For adoption

7.4.4. Ofatumumab – KESIMPTA (CAP) – EMA/VR/0000315689

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Update of section 4.6 'pregnancy' of the SmPC based on the final reports from Kesimpta Pregnancy Registry and the PRenancy outcomes Intensive Monitoring (PRIM) study.

⁷ In accordance with Article 61a (6) of Regulation (EC) No 726/2004, in line with the revised variations regulation for any submission as of 4 August 2013

Action: For adoption

7.4.5. Radium-223 – XOFIGO (CAP) – EMA/VR/0000333243

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Submission of final study report from study 20511 listed in Annex IID of the SmPC. This is a phase I biodistribution study to further characterise correlation between the extent of the disease, the dose and the distribution of radium-223 in bone metastases versus sites of impaired bone health versus normal bone structure. The Annex II is updated accordingly.

Action: For adoption

7.5. Interim results and other post-authorisation measures for imposed and non-imposed studies

7.5.1. Diroximel fumarate – VUMERITY (CAP) – EMA/PAM/0000343706

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Dennis Lex

Scope: Third interim report for registry-based PASS 272MS403 (An Observational Study Utilising Data From Big MS Data Registries to Evaluate the Long-Term Safety of Vumerity and Tecfidera) - Cat 3.

Action: For adoption

7.5.2. Pegvaliase – PALYNZIQ (CAP) – EMA/PAM/0000319171

Applicant: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Third interim study report for study BM 165-501: a multi-centre observational study to evaluate the long-term safety of subcutaneous injections of Palynziq (pegvaliase) in subjects with phenylketonuria.

Action: For adoption

7.5.3. Pegvaliase – PALYNZIQ (CAP) – EMA/PAM/0000317250

Applicant: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Third interim report for study BM 165-504: a global multicentre study to assess maternal, foetal and infant outcomes of exposure to Palynziq (pegvaliase) during pregnancy and breastfeeding.

Action: For adoption

7.5.4. Respiratory syncytial virus mRNA vaccine (nucleoside modified) – MRESVIA (CAP) – EMA/PAM/0000316615

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Assessment of Post-Authorisation Active Surveillance Safety Studies Using Secondary Data to Monitor Real-World Safety of the mRNA-1345 Vaccine for respiratory syncytial virus (RSV) in the United States and in Europe (interim results for mRNA-1345-P902 and mRNA-1345-P903).

Action: For adoption

7.5.5. Selexipag – UPTRAVI (CAP) – EMA/PAM/0000309454

Applicant: Janssen Cilag International

PRAC Rapporteur: Zoubida Amimour

Scope: Second interim Clinical study report of study AC-065A403 (EDUCATE), a category 3 PASS study (EMA/H/C/003774/MEA/003) with a data cut-off date of 11 July 2025.

Action: For adoption

7.5.6. Tezepelumab – TEZSPIRE (CAP) – EMA/PAM/0000343681

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Submission of the interim progress report for study D5180R00024, a non-interventional, multi-country Post-Authorisation Safety Study (PASS) evaluating the incidence of serious cardiac events in patients with severe uncontrolled asthma treated with tezepelumab. This PASS is listed as category 3 in the RMP.

Action: For adoption

8. Renewals of the marketing authorisation, conditional renewal and annual reassessments

8.1. Annual reassessments of the marketing authorisation

8.1.1. Chenodeoxycholic acid – CHENODEOXYCHOLIC ACID LEADIANT (CAP) – EMA/S/0000340415

Applicant: Leadiant GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.2. Idursulfase – ELAPRASE (CAP) – EMA/S/0000339599

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Liana Martirosyan

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. Susoctocog alfa – OBIZUR (CAP) – EMA/S/0000324538

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.4. Tabelecleucel – EBVALLO (CAP) – EMA/S/0000326533

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Amelia Cupelli

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.5. Zanamivir – DECTOVA (CAP) – EMA/S/0000339464

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

8.2.1. Elranatamab – ELREXFIO (CAP) – EMA/R/0000347279

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Avacopan – TAVNEOS (CAP) – EMA/R/0000340631

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.2. Finerenone – KERENDIA (CAP) – EMA/R/0000340433

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.3. Formoterol / Glycopyrronium bromide / Budesonide – RILTRAVA AEROSPHERE (CAP) – EMA/R/0000340519

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.4. Lonapegsomatropin – SKYTROFA (CAP) – EMA/R/0000339532

Applicant: Ascendis Pharma Endocrinology Division A/S

PRAC Rapporteur: Dennis Lex

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) – PREVENAR 20 (CAP) – EMA/R/0000340648

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. Rivaroxaban – RIVAROXABAN VIATRIS (CAP) – EMA/R/0000327079

Applicant: Viatris Limited

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.7. Semaglutide – WEGOVY (CAP) – EMA/R/0000336288

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.8. Somatrogen – NGENLA (CAP) – EMA/R/0000340629

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.9. Tecovirimat – TECOVIRIMAT SIGA (CAP) – EMA/R/0000340615

Applicant: Siga Technologies Netherlands B.V.

PRAC Rapporteur: Dennis Lex

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.10. Tepotinib – TEPMETKO (CAP) – EMA/R/0000339701

Applicant: Merck Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspections

Disclosure of information on results of pharmacovigilance inspections could undermine the protection of the purpose of these inspections, investigations and audits. Therefore such information is not reported in the agenda.

9.3. Others

None

10. Other safety issues for discussion requested by the Member States, CHMP or the EMA

10.1.1. Botulinum toxin type A (NAP) - IE/H/xxxx/WS/380

Applicant(s): AbbVie Limited

PRAC Lead: Eamon O Murchu

Scope: PRAC consultation on a type II national variation to update the product information regarding the risk of iatrogenic botulism, at request of Ireland

Action: For adoption

11. Scientific advice procedures

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. Draft learning pharmacovigilance map and learning priorities for 2026-2028

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.1.2. PRAC membership

Action: For information

12.1.3. PRAC Rules of procedure - revision

Action: For adoption

12.1.4. Nominated proxy

Action: For information

12.1.5. Scientific Committee Meetings – alternating face-to-face and virtual meetings schedule for 2027

Action: For adoption

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

12.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

12.3.1. Areas of collaboration between PRAC and Methodology Working Party (MWP)

PRAC lead: Ulla Wändel Liminga, Liana Martirosyan, Carla Torre

Action: For discussion

12.4. Cooperation within the EU regulatory network

None

12.5. Cooperation with International Regulators

None

12.6. Contacts of the PRAC with external parties and interaction with the Interested Parties to the Committee

None

12.7. PRAC work plan

None

12.8. Planning and reporting

12.8.1. Marketing authorisation applications (MAA) forecast for 2026 – planning update dated Q2 2026

Action: For discussion

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

12.10. Periodic safety update reports (PSURs) & Union reference date (EURD) list

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

PRAC lead: Petar Mas

Action: For discussion

12.10.3. PSURs repository

None

12.10.4. Union reference date list – consultation on the draft list

Action: For adoption

12.11. Signal management

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

12.12.3. List of products under additional monitoring – consultation on the draft list

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

12.14.2. Tools, educational materials and effectiveness measurement of risk minimisations

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

12.15.2. Post-authorisation Safety Studies – non-imposed PASS

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

12.20.1. Reflection paper on digital support to risk minimisation measures (RMMs)

PRAC lead: To be appointed

Action: For discussion

12.21. Others

12.21.1. Artificial Intelligence (AI) in pharmacovigilance guidance development

PRAC lead: Jean-Michel Dogné, Milou-Daniel Drici

Action: For discussion

12.21.2. DARWIN EU® study - Association between varicella vaccines (V), measles-mumps-rubella- varicella vaccines (MMRV), and encephalitis in paediatric recipients

PRAC Lead: Jean-Michel Dogné

Action: For adoption

12.21.3. Good pharmacovigilance practice (GVP) – mid-year update 2026

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.21.4. Guideline on good pharmacovigilance practices (GVP) Module III – Pharmacovigilance inspections (Rev 2)

Action: For adoption

12.21.5. Process for real-world interrogation network (DARWIN EU®) studies conducted for PRAC and real world evidence (RWE) – update

PRAC Lead: Liana Martirosyan

Action: For adoption

12.21.6. Transition to IRIS for initial marketing authorisation applications and pre-submission activities - update

Action: For information

13. Any other business

None

14. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

List of acronyms and abbreviations

For a list of acronyms and abbreviations used in the PRAC agenda, see:

[List of abbreviations used in EMA human medicines scientific committees and CMDh documents, and in relation to EMA's regulatory activities](#)

EU Referral procedures for safety reasons: Urgent EU procedures and Other EU referral procedures

(Items 2 and 3 of the PRAC agenda)

A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the European Union (EU). For further detailed information on safety related referrals please see: [Referral procedures: human medicines | European Medicines Agency \(europa.eu\)](#)

Signals assessment and prioritisation

(Item 4 of the PRAC agenda)

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have a comprehensive knowledge of a medicine's benefits and risks.

The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.

The evaluation of safety signals may not necessarily conclude that the medicine caused the adverse event in question. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary and this usually takes the form of an update of the summary of product characteristics and the package leaflet.

Risk Management Plans (RMPs)

(Item 5 of the PRAC agenda)

The RMP describes what is known and not known about the side effects of a medicine and states how these risks will be prevented or minimised in patients. It also includes plans for studies and other activities to gain more knowledge about the safety of the medicine and risk factors for developing side effects.

RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available.

Assessment of Periodic Safety Update Reports (PSURs)

(Item 6 of the PRAC agenda)

A PSUR is a report providing an evaluation of the benefit-risk balance of a medicine, which is submitted by marketing authorisation holders at defined time points following a medicine's authorisation.

PSURs summarises data on the benefits and risks of a medicine and includes the results of all studies carried out with this medicine (in the authorised and unauthorised indications).

Post-authorisation Safety Studies (PASS)

(Item 7 of the PRAC agenda)

A PASS is a study of an authorised medicinal product carried out to obtain further information on its safety, or to measure the effectiveness of risk management measures. The results of a PASS help regulatory agencies to evaluate the safety and benefit-risk profile of a medicine.

Product related pharmacovigilance inspections

(Item 9 of the PRAC agenda)

Inspections carried out by regulatory agencies to ensure that marketing authorisation holders comply with their pharmacovigilance obligations.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/

Article 58 procedures (Art 58)

Article 58 of Regulation (EC) No 726/2004 allows the Committee for Medicinal Products for Human Use (CHMP) to give opinions, in co-operation with the World Health Organisation (WHO) on medicinal products for human use that are intended exclusively for markets outside of the European Union (EU)